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OVERSIGHT OF VA PACEMAKER POLICY

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

NINETY-SIXTH CONGRESS

SECOND SESSION

WEDNESDAY, APRIL 23, 1980

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OVERSIGHT OF VA PACEMAKER POLICY

WEDNESDAY, APRIL 23, 1980

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The committee met, pursuant to notice, at 9:45 a.m., in room 412, Russell Office Building, Hon. Richard Stone, (acting chairman of the committee) presiding.

Present: Senators Richard (Dick) Stone, presiding, Robert T. Stafford and Alan Cranston.

OPENING STATEMENT OF HON. RICHARD (DICK) STONE, ACTING CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Senator STONE. The Senate Veterans' Committee will come to order. This morning, we are going to hear witnesses regarding the pacemaker program of the Veterans' Administration.

I want to thank Senator Stafford for participating. Senator Cranston, our chairman, will be participating and will be here shortly.

Ladies and gentlemen, what has concerned me for more than a year about the pacemaker program is whether or not veterans have safe pacemakers provided to them by the Veterans' Administration, whether the Veterans' Administration is issuing reused pacemakers, and if they are, are they safe, are they clean, do they work.

Before we proceed further, I want to thank all of the witnesses for myself, for the committee, and for all of our veterans, for their cooperation in preparing their detailed testimony; and for those who have, at their own expense, sacrificed other obligations to come to Washington to give the committee and the Veterans' Administration the benefit of the expertise.

Before I call the first witness, I would like to recall the events that have led to this hearing.

I am concerned about whether the policy of the Veterans' Administration is implemented and, if so, whether, if a pacemaker is recalled by a manufacturer as being deficient and needing some work, whether the VA has the names of all of the veterans who have been issued pacemakers by the Veterans' Administration and can readily recall them.

I am concerned about whether the implemented policy of the VA is to, on a periodic basis, check the working order of these pacemakers.

Also if a reused pacemaker is issued after a previous user has died, is the new user appropriately notified that he is or she is being issued a reused pacemaker which was used by a veteran or person who has died and are the families appropriately notified as well?

Are the financial practices of the VA with regard to pacemakers fully prudent, are all credits being taken, are money practices regarding the pacemakers correct and adequate? Because we have a commitment to the veterans of this country that the health care we provide to them is safe, clean, and proper and whether or not we keep that commitment is the purpose of today's particular oversight hearing.

Briefly, the background of this hearing is, that in May of 1979, and even earlier, I was concerned that the VA might not even have a system of proper monitoring and recall, because at that time, the Pacemaker Diagnostic Clinic of Gainesville, Fla. informed us that they were signing an agreement to set up a pacemaker monitoring system for the VA.

On May 30, I issued a news release announcing the import of that pending contract which would become effective on July 1, 1979.

As a result of my news release, veterans began to inquire about the implementation of this new monitoring service. I raised that question with PDC and received a discouraging response.

But it seemed that very few of the hospitals in the VA were availing themselves of the new system. I was told that the VA's announcement of the contract had stimulated very few of the 172 independent hospitals to acquire the improved system for monitoring veterans with pacemakers.

And I, in fact, learned that Florida's VA hospitals have lost contact with about half of their patients with pacemakers. Some of those lost patients might possibly have been wearing pacemakers that have been recalled by the manufacturer because of defects; that the VA was unable to tell those veterans that their lives could be in danger because the VA had not kept proper track of them.

So, on July 31 of last year I wrote to the Administrator, Max Cleland, asking that he investigate the telephone monitoring system and to start using it right away if it worked.

He replied on August 22 that there was no VA policy about pacemakers, but that they were working on it and would have one by October 9.

By mid-October, I had not received the VA's policy proposals and again raised the monitoring question at the October 25 joint hearing of the Senate and House Committees on Veterans' Affairs (Oversight on Admission Policies to VA Medical Care Facilities) and submitted 14 questions to the VA during that hearing, I wanted to know in these written questions how many veterans have pacemakers, how much it costs, how safe they are and how the VA was checking them.

In mid-November, the VA sent over some answers and plans for a data bank, but we still do not have a firm count of veterans with pacemakers.

In fact, responses to several of my questions indicated that improved surveillance of veterans with pacemaker implants hinged on the effective implementation of this new policy.

The VA, to its credit, has not denied that there are problems to be resolved in the area of procurement and monitoring of pacemakers. I commend the Administrator and his staff for demanding an independent Inspector General's audit of all aspects of the VA's pacemaker program.

And, today, we want to find out when the computerized data bank will be fully operational.

The Inspector General, Allan Reynolds, made his report of audit on VA procurement and monitoring of pacemaker available on February 13 of this year. The Inspector General found that the VA records were totally inadequate and that no one has responsibility for notifying veterans about pacemaker recalls. He also found that the responsibility for monitoring pacemaker patients has not been defined, and that the monitoring provided is inconsistent among medical centers.

At this point, I am going to submit for the hearing record a copy of those documents and letters.

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C., July 31, 1979.

HON. MAX CLELAND,
Administrator,
Veterans' Administration, Washington, D.C.

DEAR MAX: On May 30, 1979, my office issued a news release announcing the Veterans Administration's pending contract with the Pacemaker Diagnostic Clinic (PDC) of Gainesville, Florida (see attachment). The agreement, which was to go into effect on July 1, 1979, would create a nationwide pacemaker testing and monitoring system. Under this program veterans with pacemakers could test the effectiveness of their devices at the nearest telephone—usually without leaving their own home. In addition, information on each VA pacemaker patient would be entered into a centralized computer.

The health and safety value of a monitoring system that offers high-quality pacemaker checkups that are convenient, time saving, energy efficient and cost effective is hard to question. Veterans with defective or failed pacemakers may find themselves in life-threatening circumstances. Their safety and that of others requires that these instruments be tested regularly. There is evidence, however, that in Florida alone no more than 800 of an estimated 1,600 pacemaker recipients are actually available for check-up.

As a result of my news release, veterans are inquiring about the delivery date of this new monitoring service. I have raised the availability question with Pacemaker Diagnostic Clinic, and have received a discouraging response—the terms of the VA agreement do not encourage the immediate acquisition of the computerized monitoring system. The contract does not mandate the new program but merely authorizes each hospital to make the improvement; and, if there is a purchase of PDC's services, it must be made from funds allotted for other purposes.

I am told that under these terms few hospitals have expressed interest in improving their ability to monitor veterans' pacemakers; they say they do not have the funds. Obviously, it has not been explained to them that this home testing service would reduce costs by saving staff time, hospital resources and travel reimbursement expenses. Moreover, it is claimed that individual VA employees are covertly profiting under testing arrangements with private clinics, and will not agree to acquiring a new program, no matter what benefits result to the veterans and no matter what savings accrue to the taxpayers.

The importance of a centralized data bank of pacemaker information is also unquestionable. Florida's VA hospitals have lost contact with about 50% of their patients with pacemakers. I would hate to think how many of those veterans that the VA has lost touch with have pacemakers that have been recalled by the manufacturer because of defects. In addition, this computer could contain information that could be lifesaving to a veteran lying unconscious in a VA emergency room. The centralised data bank would be particularly important for veterans who move from state to state—say from a northern location to Florida for the winter months. To be effective, however, the data bank requires that participation of each VA hospital qualified to implant pacemakers.

Even if the foregoing claims are no more than minimally accurate, the immediate acquisition of an improved monitoring process is worthy of priority consideration. I am therefore requesting that your office investigate the worth of PDC's pacemaker monitoring system, and if its value is substantiated, take the administrative steps necessary for putting it in place without delay. I would also like to be kept informed of the VA Inspector General's investigation of fraud and abuse by certain VA employees with regard to pacemaker acquisition and testing.

I would appreciate your immediate attention to this matter. If these issues can be resolved within the VA, an independent Congressional inquiry will not be necessary.

Warm personal regards.

Most cordially,

RICHARD (DICK) STONE.

RESPONSE OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY HON. RICHARD (DICK) STONE, A U.S. SENATOR FROM THE STATE OF FLORIDA

Question 1. How many veterans are there with pacemakers?

Answer 1. The number of veterans with pacemaker implants being followed by the VA is not readily available since the control of this program has been at the local facility level. Recognizing the need for close monitoring and control of this program, the VA is currently establishing a centralized Cardiac Pacemaker Registry to identify the total cardiac pacemaker population receiving their care in VA facilities. In addition, this Registry will help improve the quality of care rendered the pacemaker recipient by facilitating follow-up monitoring, responses to FDA pacemaker recall notices, and developing trends in defects of implanted cardiac pacemakers. The Registry will also provide a data base for further research in the area of cardiac pacemaker prostheses.

Question 2. What policies govern the monitoring of veterans with pacemakers, what VA studies have been done on the issue?

Answer 2. In the past the policies governing the monitoring of veterans with cardiac pacemakers have been established at each individual medical center and have been based on the professional knowledge, experience, and expertise available at that center. In general, these policies have reflected state-of-the-art care in the cardiac pacemaker area and follow the guidelines for implantable cardiac pacemakers published by the Inter-Society Commission for Heart Disease Resources. VA Central Office has recently prepared a formal policy document (Circular) on cardiac pacemaker prostheses, the purpose of which is to establish centralized guidance concerning the acquisition and control of permanent cardiac pacemaker prostheses, their implantation in veterans who require cardiac pacemakers, and the subsequent follow-up of these veterans. This centralized policy, combined with local expertise, will enhance the overall quality of care provided the VA pacemaker recipient. The establishment of the centralized Pacemaker Registry cited in the answer to Question 1, will also assist in this enhancement of quality of care.

Several VA medical centers have conducted local pacemaker monitoring studies of an informal type. A comprehensive study, under Central Office aegis and involving a large segment of the field, should be mounted to review all aspects of this issue.

Question 3. Is there a centralized monitoring and data-gathering unit within the VA?

Answer 3. Through the recent issuance of its Circular on "Cardiac Pacemaker Prostheses" and the establishment of its centralized Cardiac Pacemaker Registry, the VA has established a centralized monitoring and data gathering system.

Question 4. What monitoring method(s) is currently in use at individual VA hospitals that are available to the veteran at the instance of a pacemaker problem?

Answer 4. There are several monitoring methods currently in use in individual VA medical centers that are available to the veteran in the event of a pacemaker problem. First and foremost among these methods is direct clinical observation and evaluation. When appropriate, telephonic monitoring may also be utilized. This telephonic surveillance may be provided by VA staff using appropriately acquired equipment, through valid sharing or other contractual arrangements, or by order against decentralized contracts established by the VA Marketing Center, Hines, Ill.

Question 5. Does the VA have a reasonable estimate of its current annual pacemaker surveillance cost?

Could this cost be reduced and technologically improved if the monitoring function were contracted out?

Answer 5. Several VA medical centers have preliminary data on their current annual pacemaker surveillance costs, but no overall estimates for the entire agency is available. Thorough evaluation and analysis of this question would be required before any comments on the relative effectiveness and/or costs of pacemaker surveillance done within the VA or by contract could be made.

Question 6. What is the number of manufacturers of cardiac pacemakers in the United States who are actively marketing pacemakers?

What is the number of different models of pacemakers currently in use in the United States today?

Answer 6. There are approximately 36 cardiac pacemaker manufacturers in the United States active in the pacemaker marketing field. Most manufacturers offer 4-10 models each, some of these with subvariants.

Question 7. How many recalls initiated by the Food and Drug Administration have occurred from 1975 to the present? What is the number of units of these recalls?

Answer 7. According to the Bureau of Medical Devices, the Food and Drug Administration, there have been 31 recalls of pacemakers since 1975. The total number of units involved in these recalls is 102,263.

The classification of these recalls were as follows:

Class I—3.
Class II—28.
Class III—0.

The FDA classifications for recalls are:

Class I—A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

Class II—A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III—A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Question 8. Are there cardiac pacemaker patients within the Veterans' Administration that currently have implanted in them models that have been recalled by the Food and Drug Administration? Are these patients currently being followed on a regular schedule to determine when life-threatening situations would occur?

Answer 8. Yes, there are some VA cardiac pacemaker patients in this category. It is VA policy that such patients be monitored on a regular basis by clinical and/or telephonic means and pacemaker replacement accomplished when indicated. The Food and Drug Administation's classification system for recalls cited in the answer to Question 7 provides helpful guidance in this area.

Question 9. How many pacemakers in the Veterans' Administration are actually in clinical testing rather than general distribution? Clinical testing meaning those pacemakers that are considered under the Device Amendments Act of 1976 as being in a clinical stage of development.

How are cardiac pacemakers chosen for implantation; by the individual stations? Are these purchases always coordinated with supply service?

Answer 9. While the exact number of pacemakers in use by the Vererans' Administration under clinical testing is not known, the establishment of a centralized Cardiac Pacemaker Registry will provide such data for future use. Presently, each medical center has accountability for the patients in its care.

There are numerous considerations that enter into the selection of a cardiac pacemaker for implantation at the individual VA medical center. Some of the more important of these considerations are the clinical status and cardiac pacemaker requirements of the patient, the training and experience of the attending cardiologist/cardiothoracic surgeon, the technical specifications of the pacemaker, and the cost of the pacemaker.

It is VA policy that all medical center purchases be coordinated through Supply Service. However, we are aware that in the procurement of pacemakers, this coordination may not have been accomplished in every situation. Specific guidelines are being developed to assure complete coordination through VA Medical Center Supply Services in the future.

Question 10. Is there a person or groups of people, or a central data bank at station available to give a position, important pacemaker parameters, or characteristics of certain cardiac pacemakers available to a station that may not be familiar with a particular brand?

Since the cardiac pacemaker is an electronic device, who gives the Veterans' Administration physician the engineering backup in terms of performance characteristics.

Answer 10. The VA Circular on "Cardiac Pacemaker Protheses" directs that each VA Medical District designate certain VA medical centers within its area of jurisdiction as Cardiac Pacemaker Prosthesis Referral Centers (CPPR Centers). Permanent cardiac pacemaker prostheses will be implanted or replaced only in such CPPR Centers. In addition, each Medical District will develop a district-wide plan for cardiac pacemaker implantation and replacement, specifying the professional expertise and the diagnostic and operative facilities available to implement the pacemaker program. Each CPPR Center will function as a repository of expertise and information concerning pacemakers. The centralized Cardiac Pacemaker Registry will also be an important source of pacemaker data, which data will be made available to the individual medical centers.

Biomedical engineers provide technical engineering back up as far as cardiac pacemakers are concerned and are available in Central Office, selected VA medical centers, and many affiliated university medical centers.

Question 11. What method(s) is used to keep up with the numerous changing characteristics of the parameters of pacing systems on an ongoing basis on all brands used by the Veterans' Administration?

Answer 11. To keep abreast of the constantly changing cardiac pacemaker field many methods are used—e.g. reading the current literature (including such specific journals as Circulation, American Journal of Cardiology, American Heart Journal, Journal of Thoracic and Cardiovascular Surgery, PACE, etc.), attendance at professional meetings, contact with colleagues, and review of manufacturers' literature. In addition, Central Office plans to issue Professional Services Letters and other reports based on data obtained from the centralized Cardiac Pacemaker Registry in an effort to inform the field of the latest developments in this area.

Question 12. Is the follow-up schedule for lithium pacemakers in the Veterans' Administration in accordance with the appropriate schedules recommended by authorities in cardiac pacemaking?

Is there consistency of monitoring schedules within Veterans' Administration hospitals?

What criteria is most important for pacemaker follow-up?

Answer 12. Although there is wide individual variation in the follow-up schedules for pacemaker patients, in general these schedules are usually consistent with the recommendations of known authorities in the field.

Since each patient should have his own individual monitoring schedule, there can be a consistency of monitoring schedules within the VA in only the broadest sense. The establishment of VA Medical District cardiac pacemaker plans and the designation of CPPR Centers will help provide somewhat greater overall uniformity in this area.

The most important criterion for pacemaker follow-up is maintenance of the clinical condition of the pacemaker patient in an optimal state. This should be accomplished by careful clinical evaluation and careful rate and ECG analysis as often as indicated.

Question 13. Is the Veterans' Administration aware of the current recommendations for pacemaker follow-up as presented by the authorities on pacemakers at the NIH meeting in March and does the Veterans' Administration system agree with those recommendations?

Answer 13. The VA is aware of these recommendations and is in agreement except that the monitoring schedules should be adopted as guidelines rather than mandated time intervals. The actual program in a specific patient should be established by the attending physician based on the patient's clinical status and requirements.

Question 14. How many physicians on the Veterans' Administration "Pacemaker Committee" attended the Sixth World Symposium on Cardiac Pacemaking in Montreal, Canada, on October 1st through the fifth?

Answer 14. One of the committee members attended the Symposium. Two other members had originally planned to attend, but had to alter their plans shortly before the meeting because of other professional duties. However, all committee members keep abreast of current cardiac pacemaker developments via the mechanisms cited in the answer to Question 11. The Veterans' Administration is fully represented at the annual meetings of the American Heart Association, American College of Cardiology, Society of Thoracic Surgeons, American Association for Thoracic Surgery, etc.

Veterans Administration
Department of Medicine and Surgery
Washington, D. C. 20420

Circular 10-79-260

November 13, 1979

SUBJ: Cardiac Pacemaker Prostheses

TO: Directors of VA Medical Centers, Medical and Regional Office Centers, Domiciliary, Outpatient Clinics and Regional Offices with Outpatient Clinics

1. Purpose. The purpose of this Circular is to establish policy for the acquisition and control of permanent cardiac pacemaker prostheses, their implantation in veterans who require cardiac pacemakers, and the subsequent follow-up of these veterans. This Circular also makes provision for the collection of data pertaining to cardiac pacemakers and the exchange of this information with other health care organizations and appropriate federal authorities. In addition, this Circular provides for the establishment of Cardiac Pacemaker Prosthesis Referral Centers (CPPR Centers).

2. Goals and Objectives. Cardiac pacemaker prostheses first became a therapeutic option in 1959. Currently more than 3000 cardiac pacemaker prostheses are supplied to veterans annually. Future participation of the Veterans Administration in utilization and management of these prostheses may be expected to grow proportionately to the degree to which older veterans with degenerative heart disease are treated. The Veterans Administration will provide eligible veterans who have cardiac diseases requiring cardiac pacemakers with prostheses of the highest quality. Suitable administrative reviews and appropriate professional supervision of veterans who have been provided with cardiac pacemakers will be established. Results of cardiac pacemaker performance will be documented through a registry.

3. Cardiac Pacemaker Prostheses.

a. Description. Cardiac pacemaker prostheses include two functionally inseparable components: the pulse generator and the lead system. Pulse generators consist of a specially manufactured electrical storage battery and an electronic circuitry element. Batteries originally were made of mercury-zinc cells, whose projected functional life was in the range of 36 to 60 months. Recently lithium-type batteries with much longer calculated life have become available. Atomic batteries also are in use. The lead system consists of conductive material ensheathed in flexible, biologically inert plastic. At one end is a connector to the pulse generator and at the other end of the lead is an electrode element which makes permanent contact with appropriate heart tissue. Leads may be anchored to the atrium, to the ventricle, or to both. Cardiac pacemakers may be of a fixed rate (continuous) or they may be of the demand type (inhibited or triggered). Many of these types are programmable.

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b. Patient Selection. There is wide variation among physicians regarding the clinical indications for providing electronic cardiac pacing. In the absence of general medical contraindications, pacemaker prostheses are appropriate for specific disorders of cardiac rate and rhythm which cause major symptoms or pose a threat to life. To reach a decision on this issue requires highly specialized professional skill and experience and presumes the availability of adequate diagnostic equipment.

c. Prosthesis Selection. This process involves both professional and administrative determinations.

(1) At each medical center the physician most likely to be fully knowledgeable about both the patient and pacemaker prostheses is likely to be a cardiologist or cardiothoracic surgeon. He must work in close collaboration with the Supply and Prosthetics Services in the acquisition of these prostheses.

(2) After implantation, a complete prosthesis profile must be established for each veteran currently a Veterans Administration patient. The responsibility for this rests with the Cardiology Section at each CPPR Center, as designated in accordance with paragraph 4 of this Circular. This applies equally for prostheses which may have been provided for veterans by non-VA health care facilities and whose long term cardiac care is assumed by the VA medical center.

d. Procedure Selection. The techniques used to implant, remove or replace cardiac pacemakers and the specialized unit of the medical center to be employed for this purpose will be determined by the cardiothoracic surgeons and/or the cardiologists at the CPPR Centers.

e. Prosthesis Malfunction. Although painstaking precautions are taken by manufacturers, the Food and Drug Administration, and independent testing agencies, critical malfunctions of cardiac pacemaker prostheses occur occasionally. The most common of these relate to pulse generators. Formerly the main problem was power source depletion prior to the anticipated expiration date. With the new lithium pacemakers this problem may decrease. Another problem is unanticipated short-out of the electronic circuitry. This can be due to interruption of connections or result from molecular migration of solder metal. Leads may also fracture or lose their insulation or electrodes may disconnect from the heart. All exchanges made with the manufacturer as a result of prosthesis malfunction will be handled through the Supply Service.

4. Plan for Monitoring Cardiac Pacemaker Prostheses. All veterans who have received cardiac pacemaker prostheses must have adequate follow-up surveillance. This will be provided under VA auspices if appropriate or by referral to another acceptable health care provider.

a. District Plan. The Medical Districts will designate VA medical centers within their area of jurisdiction as Cardiac Pacemaker Prosthesis Referral Centers (CPPR Centers). Permanent cardiac pacemaker prostheses will be implanted or replaced only in the CPPR Centers. Within one month of the issuance of this Circular each Medical District will develop and submit to the ACMD for Professional Services (11/111) a district-wide plan for cardiac pacemaker implantation and replacement. This plan shall be implemented when notified of approval by the Veterans Administration Central Office. The plan should specify the professional expertise and the diagnostic and operative facilities available to implement this portion of the pacemaker program. Each Medical District will regularly review its plan and yearly submit any major revision to the ACMD for Professional Services (11/111).

b. CPPR Center Follow-up Surveillance Plan.

(1) Follow-up surveillance methods and schedules are determined by the clinical status of the patients. Direct clinical surveillance will be required for all patients during the first weeks after implantation of the prosthesis. Long range patient surveillance will be established by whatever method is determined appropriate by the cardiologist or cardiothoracic surgeon attending the patient. After the patient's rate and rhythm disorder has stabilized, if there is no other significant clinical problem and it is in the best interest of the patient, telephonic surveillance may be employed.

(2) Telephonic surveillance may be provided by one of the following methods:

(a) Monitoring by VA staff using equipment previously acquired or acquired in the future under the Federal Supply Schedule for pacemaking devices. This is confined to past and future acquisitions where the transmitter is provided with the pacemaker by the manufacturer at the time of procurement for use with its product only.

(b) From locally awarded contracts for telephonic monitoring which preexisted Decentralized Contract #V797P-2571A effective July 1, 1979, through June 30, 1980. If such contracts expire before June 30, 1980, they will not be renewed. Service will be obtained from established Decentralized Contracts. This includes all agreements made as a part of sharing or other contractual arrangements.

(c) By order against Decentralized Contracts established by the VA Marketing Center.

(3) Selection of an appropriate follow-up surveillance program is delegated to the CPPR Centers. It is anticipated that the majority of the cardiac pacemaker patients will be followed by the CPPR Centers. In the event that a patient receives follow-up surveillance in a medical facility other than the designated CPPR Center, all information relative to this patient will be forwarded to the CPPR Center for maintenance of the registry referred to in the next paragraph. Within two months of the issuance of this Circular, the CPPR Centers identified in accordance with paragraph 4 will submit their proposed Cardiac Pacemaker Prosthesis Surveillance Plans through their Medical Districts to the ACMD for Professional Services (11/111) for approval. Each such medical center will regularly review its follow-up surveillance plan and yearly submit any major revisions through its Medical District to the ACMD for Professional Services (11/111) for concurrence.

(4) The CPPR Centers identified in accordance with paragraph 4 will establish and maintain the registry referred to in Circular 10-79-268 and will furnish the required reports. The VA Form 10-5548 will establish an individual file for each cardiac pacemaker recipient followed by the facility. This file will be the only file maintained at the facility and will be retained in the clinic office through which follow-up surveillance is maintained. The documentation in this file does not substitute for the required recording of significant events in the patient's medical record. The Chief of the Cardiology Section, or a designee, will review the file and all other pertinent follow-up surveillance data quarterly and indicate having done so by an appropriately dated annotation of the file. When a patient is lost to follow-up, transfers to the care of a private physician or to another VA medical center, or expires, the pacemaker surveillance file and registry records will be combined with the patient's medical record. Medical Administration Service will be responsible for effecting the transfer of the pacemaker file and the medical records at the time of patient transfer to another VA medical center. The registry is an essential element of the cardiac pacemaker prosthesis program and will be prepared and maintained as carefully and as accurately as possible.

(5) Full and prompt investigation of all deviations from normal pacemaker prosthesis function and all patient symptoms which may be indicative of prosthesis malfunction will be made by the physician supervising the surveillance program for that patient at each VA medical center, and appropriate professional action will be taken to correct each problem. Whenever a private physician refers a patient to a VA medical center for health problems which such physician states to be attributable to prosthesis malfunction, the functional status of the prosthesis will be determined by a physician knowledgeable about cardiac pacemakers before the veteran is released from the medical center. All deaths of veterans with cardiac pacemaker prostheses will be reviewed by the VA medical

center to determine whether prosthesis malfunction may have been a contributing factor. If an autopsy is authorized, the whole prosthesis will be retrieved for study. If not destroyed during the study, a pacemaker may be used for research purposes or be sent to the Supply Service for return to the manufacturer for credit if the unit has potential value.

(6) The results of tests performed on failed cardiac pacemaker prostheses will be reported semiannually by VACO Supply Service to the ACMD for Professional Services (11/111). Since the overall regulatory responsibility over manufacturers of cardiac pacemaker prostheses is vested in the Food and Drug Administration, trend data perceived from the analysis of failed cardiac pacemaker prostheses will be reported to that agency. The VA Marketing Center, Hines, Illinois, will also transmit to VA medical centers all pertinent information pertaining to recall actions proposed or initiated by the Food and Drug Administration.

. Central Office Management.

a. The day-to-day professional supervision of activities relating to cardiac pacemaker prostheses is the responsibility of the Office of the Assistant Chief Medical Director for Professional Services (11/111). Registry-generated data will be reviewed on a continuing basis and periodic status reports will be developed. However, many other elements of Central Office are also involved. For proper coordination a VACO Cardiac Pacemaker Prosthesis Committee will be established by the ACMD for Professional Services. This committee will meet at least semiannually to review the status of cardiac pacemaker implantation, replacement and follow-up at field facilities, evaluate the costs of prostheses, and inquire into any emerging patterns of prosthesis malfunction or other reasons for untoward events related to cardiac pacemaker utilization by veterans. An annual report to the Chief Medical Director will be developed covering these areas.

b. Central Office staff will maintain close liaison with appropriate staff of the Food and Drug Administration, National Institutes of Health, and the National Bureau of Standards to ensure full and prompt exchange of information which may not yet be available in the medical literature. Information thus obtained will be disseminated to VA medical centers. Additional liaison will be established with appropriate staff of the Department of Defense to ensure uniformity of policies pertaining to cardiac pacemaker utilization and follow-up.

c. Inquiries regarding this circular may be directed to Dr. Gerrit Schepers, Medical Service (111), (FTS 389-2550).

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REPORT OF AUDIT

PROCUREMENT AND MONITORING OF PACEMAKERS

Office of Inspector General
Office of Audit

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AUDIT ON THE PROCUREMENT AND MONITORING OF PACEMAKERS

OFFICE OF AUDIT
PROJECT NO. 101A-79-42

FEB 13 1980

EXECUTIVE DIGEST

INTRODUCTION

The purpose of this audit was to review the pacemaker procurement and monitoring procedures to: (1) determine the VA's vulnerability to fraud and abuse in the pacemaker program; (2) determine if there are any indications of fraud and abuse in the pacemaker program; (3) determine whether the VA is paying the lowest possible price for the pacemakers purchased; (4) determine the adequacy of guidelines and controls for acquiring pacemakers and monitoring services; and, (5) determine the adequacy of guidelines and controls for monitoring pacemaker patients and processing pacemaker recalls.

The audit was conducted at VA Central Office and at eight VA Medical Centers from August 27 through September 21, 1979. Areas of inquiry included: analysis of purchases of pacemakers and monitoring services; effectiveness of policy and procedures on pacemaker recalls; methods of monitoring patients; and, comparison with other health care providers.

RESOURCES

In Fiscal Year 1978, the VA purchased approximately 3,000 pacemakers at an approximate cost of $6 million. The cost of monitoring pacemaker patients has not been determined.

CONCLUSIONS

Specific instances of fraud in the pacemaker program were not identified during the audit; however, the pacemaker program is vulnerable because controls are not adequate for the requisition, receipt, stocking, and disposition of pacemakers. Three specific instances of serious irregularities in the procurement and monitoring of pacemakers have been alleged by non-VA sources and are under investigation. The VA could reduce its pacemaker expenditures by purchasing through competitive bid procedures; by obtaining and collecting credits for removed pacemakers; and by recycling pacemakers, if appropriate. Service to pacemaker patients can be standardized among medical centers by defining the VA's responsibility, determining appropriate monitoring procedures and by improving the communication of recall information, and establishing a system to identify patients affected by recalls.

The Department of Medicine and Surgery is in the process of providing specific guidelines on the pacemaker program. This agency policy is expected to address several areas discussed in this report.

RESULTS OF AUDIT

MAJOR FINDINGS	MAJOR RECOMMENDATIONS
Medical centers are using different criteria in selecting pacemakers, different procurement methods, and paying a wide range of prices for pacemakers. The Denver VA Medical Center received competitive bids which were up to $800 per unit lower (7 to 40 percent) than prices paid by other medical centers (pages 6 and 9).	Apply the most effective policies and procedures to assure that quality pacemakers are purchased at the best possible prices throughout the VA system.
The Minneapolis VA Medical Center is removing and recycling pacemakers from deceased patients. This procedure resulted in savings of approximately $21,000 in Fiscal Years 1978 and 1979. If this is an acceptable practice, implementation at all medical centers would reduce pacemaker expenditures (page 10).	Determine if recycling pacemakers is an acceptable practice and, if so, provide medical centers with guidelines on the necessary criteria and procedures.
Pacemaker requisition procedures currently used result in overlapping functions and unnecessary duplication of effort. Up to three different employees may contact a sales representative to order one pacemaker. Personnel sign for receipt of pacemakers that they have not actually received or inspected (pages 13 and 15).	Define the roles of services involved in the pacemaker requisition process and establish controls on the pacemaker receipt process.
Medical centers maintain pacemaker inventories either by purchasing stock or on consignment. Inventory control records and security are not adequate. The average inventory is 5 units and ranges from 1 to 15 units with up to 7 different brands and 10 different models at one medical center. Inventory with expired shelf life was found at two medical centers (page 17).	Determine the propriety of maintaining pacemaker inventories and, if appropriate, define acceptable inventory methods, records, levels and security.

MAJOR FINDINGS	MAJOR RECOMMENDATIONS
Medical centers do not have adequate controls to ensure that the VA requests, receives, and applies all possible credits due for pacemakers removed (page 20).	Establish and implement controls to ensure that credits are requested, received, and applied.
The VA has not established adequate records systems or procedures to protect patients affected by pacemaker recall. Communication of recall information, identification of affected patients, and communication of internally identified defective pacemakers is not adequate (page 31).	Develop a system to communicate all recall information to appropriate staff, to trace serial numbers of pacemakers to a specific patient, and communicate information on internally identified pacemakers to a responsible office.
The responsibility of the VA for monitoring pacemaker patients has not been defined, and monitoring provided is inconsistent among medical centers (page 26).	Define the VA's responsibility to pacemaker patients, determine appropriate monitoring procedures, and distribute this information to all VA Medical Centers.

CORRECTIVE ACTIONS

The Chief Medical Director agreed with all recommendations and has issued some policies on the pacemaker program. These policies include: developing a pacemaker registry at each medical center and a central registry at central office; establishing a prosthesis profile for each pacemaker patient who is currently a VA patient; determining that all veterans who have received pacemakers must have adequate follow-up surveillance either under VA auspices, or by referral to another acceptable health care provider; requiring direct clinical surveillance for all patients during the first weeks after implantation; developing surveillance plans; including both professional and administrative staff in pacemaker selection; and, including Supply Service when pacemaker exchanges are made with the manufacturer. The Chief Medical Director commented on the practice of removing and recycling pacemakers from deceased patients and these comments are included in the report. The report has also been transmitted to the General Counsel for determination of the VA's legal liability in the pacemaker program.

Chapter I

INTRODUCTION

Purpose

The Inspector General initiated this audit following the Administrator's request that an investigation be conducted on allegations of fraud and abuse relating to pacemaker acquisition and monitoring. The specific allegations are under investigation by the Office of Investigation. The purpose of this audit was to review the pacemaker procurement and monitoring procedures to: (1) determine the VA's vulnerability to fraud and abuse in the pacemaker program; (2) determine if there are any indications of fraud and abuse in the pacemaker program; (3) determine whether the VA is paying the lowest possible price for the pacemakers purchased; (4) determine the adequacy of guidelines and controls for acquiring pacemakers and monitoring services; and, (5) determine the adequacy of guidelines and controls for monitoring pacemaker patients and processing pacemaker recalls.

Background

Pacemakers, which became available about 1959, are biomedical devices which keep hearts beating by sending a small electrical stimulus into the heart muscle. The two main components of a pacemaker are the electrode lead and the pulse generator. The lead is connected to the pulse generator and makes permanent electrical contact with the heart muscle.

The pulse generator contains electronic circuitry and an electrical storage battery. Batteries were previously made of a mercury-zinc alloy and were expected to last three to five years. Lithium batteries, which have been on the market for about three years, have an expected life range from 5 to 15 years. Nuclear batteries have also been introduced recently and have a life expectancy which may exceed 100 years.

According to information developed by the Department of Medicine and Surgery, 104 VA Medical Centers purchased 3,049 pacemakers in Fiscal Year 1978 at a cost of $5,993,334. Over 50 percent of these pacemakers were purchased from Medtronic, Inc., which had over 50 percent of the worldwide pacemaker market until 1977. At that time, they had a major recall and their market share dropped to about 35 percent. Other major VA pacemaker suppliers in Fiscal Year 1978 were: Cardiac Pacemakers, Inc., (19 percent); Intermedics Inc., (19 percent); and Cordis Corporation, (8 percent). Forty-four of the 104 medical centers purchased all of their pacemakers from one company only.

Managing pacemaker recalls and determining when the battery must be replaced are two major problems associated with pacemakers. According to Food and Drug Administration statistics, there have been 31 recalls of pacemakers since 1975 with a total of 102,263 units included in these recalls. Recall notices recommend returning all existing stock and either monitoring pacemakers already implanted more frequently or replacing the pacemaker. The recall in 1977 by Medtronic, Inc., resulted in the replacement of pacemakers for 451 patients at 69 VA Medical Centers.

Monitoring of the pacemaker is required to ensure that the pacemaker is functioning properly and to determine if the battery is depleting. At least three pacemaker manufacturers, including the leading supplier of pacemakers to the VA, provide free monitoring equipment and/or services with pacemaker purchases. The VA awarded a decentralized contract for monitoring services to Pacemaker Diagnostic Clinic of America, Inc., effective July 1, 1979.

The information presented in this report reflects the situation at the time of the audit. The Chief Medical Director has issued specific policies on the pacemaker program and is in the process of developing additional policies. Policies issued include: developing a pacemaker registry at each medical center and a central registry at central office; establishing a prosthesis profile for each pacemaker patient who is currently a VA patient; determining that all veterans who have received pacemakers must have adequate follow-up surveillance either under VA auspices, or by referral to another acceptable health care provider; requiring direct clinical surveillance for all patients during the first weeks after implantation; developing surveillance plans; including both professional and administrative staff in pacemaker selection; and, including Supply Service when pacemaker exchanges are made with the manufacturer.

Scope and Audit Methodology

To evaluate controls associated with pacemaker activities, audit emphasis was placed in the following areas:

1. Analysis of purchases for pacemakers and monitoring services;
2. Analysis of controls over requisition, receipt, inventory and disposition of pacemakers;

3. Determination of the effectiveness of policy and procedures for managing pacemaker recalls;

4. Review of the methods of monitoring pacemaker patients; and,

5. Comparison of VA pacemaker purchases and monitoring to other health care programs.

Information on pacemaker purchases and monitoring was gathered in VA Central Office from August 22 to August 31, 1979. Pacemaker implant data for Fiscal Years 1978 and 1979 (first three quarters) was obtained from the computerized patient treatment file for selected medical centers. The audit team analyzed this information and developed an audit plan.

The audit plan was tested at the Richmond VA Medical Center from September 4 through September 6, 1979. After refining the audit plan, teams conducted audits at the following medical centers:

VA Medical Centers	Period
Denver, Colorado	September 10-14, 1979
Philadelphia, Pennsylvania	September 10-14, 1979
Portland, Oregon	September 10-14, 1979
James A. Haley Veterans' Hospital, Tampa, Florida	September 10-14, 1979
Hines, Illinois	September 17-21, 1979
Memphis, Tennessee	September 17-21, 1979
Minneapolis, Minnesota	September 17-21, 1979
Wadsworth, Los Angeles, California	September 17-21, 1979

Selected information was obtained by an Office of Investigation team at the Brooklyn VA Medical Center and is included in this report.

Information on pacemaker procurement and monitoring was also obtained from the following health care providers:

Kaiser Permanente Medical Care Program of Southern California
Department of the Army Surgeon General's Office
National Naval Medical Center
Walter Reed Army Medical Center
Hospital of the University of Pennsylvania
Medical College of Pennsylvania
Stritch School of Medicine of Loyola University
Tampa General Hospital
University of California at Los Angeles Medical Center
University of Colorado General Hospital
University of Tennessee Medical Center
University of Minnesota Hospital
University of Oregon Health Sciences Center

Summary of Findings

The audit team did not find specific instances of fraud at the medical centers visited; however, the pacemaker program is vulnerable because controls are inadequate. Controls need strengthening for the requisition, receipt, stocking, and disposition of pacemakers. Current procurement practices result in individual medical centers paying different prices for the same pacemaker brands and models. This indicates that the VA is not obtaining the most advantageous price. The criteria and methods used for monitoring pacemaker patients vary among VA Medical Centers. Also, the medical centers have not established adequate records or procedures to identify and protect pacemaker patients affected by recalls.

Chapter 2

PACEMAKER SELECTION AND PROCUREMENT

There is no VA policy for the selection and procurement of pacemakers.[1] As a result, the team found that the eight medical centers audited are using different criteria in the selection of pacemakers, are using different methods of procurement, and are paying a wide range of prices for pacemakers.

Physicians are directly involved in selecting the brand of pacemaker to be used at seven of the medical centers audited and at the Richmond and Brooklyn VA Medical Centers. This often includes direct contact with pacemaker sales representatives. Since this is a highly competitive industry, this method of selection leaves physicians open to allegations of "kickbacks" and other irregularities. In addition, physicians are unaware of or do not use the most cost effective methods of procurement. Consequently, the VA does not always receive the best product at the best possible price.

Pacemaker Selection and Procurement by Other Health Care Organizations

To determine how other health care providers procure pacemakers, inquiries were made to the Kaiser Permanente Medical Programs of Southern California, to the Departments of Army and Navy, and to hospitals affiliated with the eight VA Medical Centers audited.

Kaiser Permanente Medical Programs purchased all pacemakers from Medtronic, Inc., until about two or three years ago. After Medtronic, Inc. experienced a major recall, Kaiser physicians decided that pacemakers should be purchased from more than one manufacturer to avoid the same impact when recalls occur in the future. These physicians now provide the Kaiser Director of Purchasing with the names of four to six firms from which satisfactory pacemakers can be purchased. Kaiser invites and receives bids annually from these firms. About 80 percent of all its pacemakers are purchased under contract. Exceptions are permitted when the attending physician justifies another firm's pacemaker.

Personnel at the Department of the Army Surgeon General's Office, the National Naval Medical Center, and the Walter Reed Army Medical Center stated that there are no centralized guidelines for the selection and procurement of pacemakers in their systems.

[1] The Department of Medicine and Surgery issued Circular 10-79-269 on November 13, 1979. This circular is about cardiac pacemaker protheses and addresses pacemaker selection.

The selection of pacemaker brands is largely the decision of individual physicians at the hospitals.

Within each affiliated hospital, selection of pacemaker brand and model was largely a determination of the individual physician. Once selected, most hospitals purchase pacemakers and bill the patients. To reduce their inventory costs, some physicians and hospitals receive pacemakers on consignment from sales representatives and pay for them at the time of implant. Private medical insurers, Medicare, and Medicaid provide reimbursement to patients for the expense of the pacemaker, implant procedures, and followup monitoring services.

Pacemaker Selection and Procurement in the Veterans Administration

Several factors affect the selection and cost of pacemakers. Each manufacturer normally produces a variety of models including those that create an impulse at a fixed rate, models that create an impulse only when the heart does not function properly, and models that can be programmed at different rates. The estimated life spans of pacemaker batteries vary. Normally, the longer the expected life of the pacemaker, the higher the cost. Manufacturers sometimes include "free" equipment and/or services with pacemaker purchases which may inflate the basic cost of their pacemakers.

At seven of the medical centers audited, the surgeon and/or cardiologist selects the pacemaker brand and model to be used. At the Denver VA Medical Center, the brand is selected through competitive bids, and the particular model is selected by the physicians. Criteria used for selecting specific brands and models varies among medical centers. One medical center uses one brand exclusively for "teaching needs," while others use assorted brands for "teaching needs." Other selection criteria include the patient's physical condition, the perceived quality of the particular brand, the service provided by the sales representatives, the patient's life expectancy, and the cost of the pacemaker. Physicians at four medical centers stated they do not consider cost when selecting pacemaker brands or models.

For the eight medical centers audited, the average price paid for pacemakers purchased in Fiscal Year 1979 ranged from $1,521 at Minneapolis to $2,473 at Hines as shown in Table A. None of the eight medical centers had contracts or sharing agreements with non-VA medical centers for pacemaker implants or purchases. According to information developed by the Department of Medicine and Surgery, the VA paid an average of $2,029 per pacemaker purchased in Fiscal Year 1978.

TABLE A

AVERAGE PRICE PAID FOR PACEMAKERS

VA Medical Center	Fiscal Year 1978	First 3 Quarters Fiscal Year 1979
Denver, Colorado	$1,888	$2,028
James A. Haley Veterans' Hospital	1,895	1,692
Hines, Illinois	2,260	2,473
Memphis, Tennessee	1,944	1,917
Minneapolis, Minnesota	1,547	1,521
Philadelphia, Pennsylvania	1,970	2,254
Portland, Oregon	2,175	2,325
Wadsworth, California	1,851	2,255

In addition to price variances due to different brand and model selection, the price for the same brand and model varied from medical center to medical center, as shown in Table B.

TABLE B

COMPARISION OF PURCHASE PRICES AS OF AUGUST 1979

Manufacturer	Model	List Price	VAMC Denver	VAMC Hines	VAMC Memphis	VAMC Minneapolis	VAMC Phila.	VAMC Portland	VAMC Wadsworth
Cardiac Pacemakers, Inc.	501/502					$ 750			
	505/605	$2,695		$2,795	$2,695				
	507/607	2,195	$1,500		2,195			$ 1,650	
	508/608	1,450	1,325		1,450				
Medtronic, Inc.	5972/5973	2,395		2,295			$2,395		
	5982/5983	1,495		1,495		1,695			
	5988/5989	2,395		2,395			2,395		
	5994/5995	2,195		2,195		2,495	2,195		
Telectronics Pty. Ltd.	140B	1,580	1,195	1,580					
	160B	2,108		2,108	2,108				$2,195
	250B	1,932	1,450						

Note: VAMC at Tampa is not included since they did not purchase any of these brand and model numbers.

There are various reasons for these price differences. Although it is the VA's major supplier, Medtronic, Inc. provides a minimal discount. Prior to April 1979, the VA was paying the standard list price. The only apparent savings was a $100 list price transmitter which was furnished free upon request. The Philadelphia Medical Center purchased 88 Medtronic, Inc. pacemakers in Fiscal Year 1978 and the first three quarters of 1979; however, they did not obtain the free transmitters because they were not using telephone monitoring at the time. Nevertheless, there were no attempts to negotiate a lower price which excluded transmitters. In April 1979, Medtronic, Inc. published a special U.S. Government Hospital price list which reflects a 12 percent discount for 4 of its 12 pacemaker models.

The Denver VA Medical Center awarded a station contract for pacemakers that resulted in significant cost savings. Previously, this medical center used one brand exclusively; however, the professional staff decided that other pacemaker manufacturers were comparable in quality and that competitive bids would result in reduced costs. The professional staff determined what specifications/models were acceptable and comparable. A contract was awarded for two Telectronics pacemaker models at a cost of $1,325 and $1,500. These prices were $800 (40 percent) and $745 (34 percent) per unit lower than the prices on the Telectronic federal supply schedule in effect at that time. Bids received from Cardiac Pacemakers, Inc., were $695 (32 percent) and $125 (7 percent) lower than the price lists used at other VA Medical Centers. This contract also allowed for another cost saving feature, a "contributory program" in which the successful bidder provides pulse generators and leads at no cost for patients with a "poor diagnosis." The Chief of Cardiothoracic Surgery projected a savings of $27,660 on the 36 pacemaker systems expected to be purchased this year.

Minneapolis VA Medical Center achieved a considerable cost savings by purchasing a model of Cardiac Pacemakers, Inc. that was being phased out by the company. Although these pacemakers had not reached their "do not use" date, they were implanted in patients with a short life expectancy.

Supply Services' involvement in the procurement process is limited at eight of the medical centers. Although the purchase order request submitted to Supply Service identifies a particular pacemaker brand, there is no justification for purchasing from this manufacturer only. Supply Service normally just calls the sales representative to determine the price and provides the company with a purchase order number. Three medical centers paid more than the list price for models because supply personnel relied on quotations from sales representatives rather than the current price lists.

Supply Services' involvement in pacemaker procurement should be increased. Federal Procurement Regulations, Title 41, Subpart 1-3.1, state:

> When a proposed procurement appears to be noncompetitive, the procuring activity is responsible not only for assuring that competitive procurement is not feasible, but also for acting whenever possible to avoid the need for subsequent noncompetitive procurements. This action shall include both examination of the reasons for the procurement being noncompetitive and steps to foster competitive conditions for subsequent procurements...

The Veterans Administration is not receiving the best possible prices for pacemakers partly because procurement regulations are not followed at the VA Medical Centers. The procurement of pacemakers is largely in the hands of individual physicians who are not specialists on VA procurement methods. Supply Services' involvement in the pacemaker procurement process is limited and competitive bids have not been received. Where medical center staff have actively sought the best possible prices, significant cost savings have been realized. Due to the success of some medical centers in acquiring pacemakers at reduced prices, either agency contracts or individual medical center contracts for pacemakers will substantially reduce pacemaker costs. The large volume of pacemakers purchased by the VA should provide further leverage in receiving reduced rates from pacemaker manufacturers.

RECOMMENDATION NO. 1:

That the Department of Medicine and Surgery apply the most effective policies and procedures to assure that quality pacemakers are purchased at the best possible prices throughout the VA system.

Recycling Pacemakers

Physicians at the Minneapolis VA Medical Center have taken an additional cost saving step. Pacemakers are recovered from deceased patients and reused. To be considered for reuse, the pacemaker must have been implanted for a relatively short period of time, usually less than 90 days. The patient must also have been monitored closely by the medical center staff. The pacemaker is recovered and sent to the medical center's biomedical engineer for testing. If in good working order, the pacemaker is sterilized and implanted in a patient with a short life expectancy. The audit team identified

14 patients who received recycled pacemakers during Fiscal Years 1978 and 1979. This procedure resulted in a savings of approximately $21,000.

Staff at VA Central Office, the affiliated hospitals, and the other VA Medical Centers visited indicated that pacemakers are not normally reused in humans. The Department of Medicine and Surgery, in conjunction with the General Counsel's staff, should review this practice to determine if it is medically and legally proper. If recycling pacemakers is an acceptable practice, the Department of Medicine and Surgery should provide guidelines for implementation at all VA Medical Centers to reduce pacemaker expenditures while assuring an acceptable level of patient safety.

RECOMMENDATION NO. 2:

That the Department of Medicine and Surgery and the General Counsel determine if recycling pacemakers is an acceptable practice and, if so, provide medical centers with guidelines on the necessary criteria and procedures.

CHIEF MEDICAL DIRECTOR'S COMMENTS:

We will take necessary action to fully implement all report recommendations with exception of Recommendation No. 2. Although we concur with the recommendation to determine if recycling pacemakers is an acceptable practice and believe such recycling is cost containing and technically not different from other types of cadaver transplantations, we cannot agree to its adoption as DM&S policy. The potential negative public relations impact of implanting "used" or "second hand" items could have a deleterious effect on patient morale and the doctor - patient relationship. Rather, we recommend exploring the possibility of recycling pacemakers back through their manufacturers for appropriate credit and then implanting such pacemakers only if they are reissued by the company under a full new item warranty.

OFFICE OF AUDIT COMMENTS:

The Chief Medical Director's response will be considered a concurrence after a policy approved by the General Counsel is distributed to all VA Medical Centers.

Chapter 3

CONTROLS OVER PACEMAKER REQUISITION, RECEIPT, INVENTORY, AND DISPOSITION

The controls over local medical center pacemaker requisition, receipt, inventory, and disposition need improvement. The Department of Medicine and Surgery has not developed guidelines covering these processes, resulting in medical centers performing these functions in different ways with varying degrees of effectiveness.[2 Pacemaker requisition procedures currently used result in overlapping functions and unnecessary duplication of effort. Personnel at some medical centers sign for receipt of pacemakers without physically receiving or inspecting them upon delivery. Medical centers have pacemaker inventories but do not maintain adequate security or inventory control records and do not determine appropriate inventory mix or levels. The medical centers also do not have adequate controls to ensure that the VA receives all credit due for pacemakers returned to manufacturers.

Pacemaker Requisition Procedures

The procedures used to order pacemakers varied at the eight medical centers, depending both on the methods used to choose pacemakers and the method of maintaining pacemaker inventories. The responsibilities for ordering pacemakers are not defined, resulting in overlapping functions and unnecessary duplication of effort by medical center personnel.

Because the physicians generally select the type and brand of pacemaker, the basic involvement of other services, such as Supply and Prosthetics, is to process the paperwork needed to complete the purchase order. Professional staff often order pacemakers by phone to expedite delivery. Therefore, the formal written purchase orders are often prepared after delivery or implant. This is done although seven of the eight medical centers normally maintain pacemaker inventories to prevent such delays.

The Hines VA Medical Center has a local policy identifying pacemakers as a prosthetic item and describing the procurement process. This policy states that the type of pacemaker to be implanted will be determined by the Chief of Thoracic Surgery. In fact, the cardiologist makes the final determination on the type of pacemaker to be implanted. Following each implant, Surgical

[2] The Department of Medicine and Surgery issued Circular 10-79-269 on November 13, 1979. This circular is about cardiac pacemaker prostheses and addresses the disposition of pacemakers.

Service prepares a VA Form 10-2431, Request for Prosthetic Service, to replenish the stock and forwards it to the Prosthetics Clerk. Following determination of eligibility, the Prosthetics Clerk prepares the Request and Receipt for Prosthetic Appliance or Service, VA Form 10-2529, and delivers it to Supply Service. This form is made out in the name of the patient who has received the pacemaker implant. The policy states that rapid processing, procurement, and delivery to Surgical Service is imperative, but does not address the actual practice of maintaining an inventory. The local policy describes pacemakers as a prosthetics item to be obtained by Prosthetics Service. Pacemaker funds are included in Prosthetics Service's budget. However, physicians, supply and prosthetics personnel stated that Prosthetics Service's involvement is not actually necessary and should be eliminated from this process.

At the Portland VA Medical Center, cardiology staff frequently call the sales representative directly to place an order to replenish pacemaker stock when an implant is performed. Cardiology Service personnel then contact Prosthetics Service to provide information on the brand, model, and patient's name for whom the implant was done. Prosthetics Service personnel then call the sales representative to place the order and also prepare a written request for prosthetics (VA Form 10-2529) in the name of the patient who received the implant, and forward the request to Supply Service. The purchasing agent in Supply Service then calls the sales representative to confirm the estimated price and to provide the representative with a purchase order number.

The Memphis and Brooklyn VA Medical Centers stock inventory on consignment and orders for pacemakers are initiated after they have been implanted in patients. At the Brooklyn VA Medical Center, the purchase request is initiated in Surgical Service and sent to the Prosthetics Activity. The purchase request identifies the patient, brand, and model number of the implanted pacemaker. From this document, prosthetics personnel initiate the written request, VA Form 10-2529, and send it on a "rush" basis to Supply Service personnel, who place the order with the company. The remaining medical centers, except Philadelphia, use a similar requisition process.

The Philadelphia Medical Center has eliminated Prosthetics Service's involvement in the pacemaker requisition process. Surgical Service, which maintains a specific fund control point for pacemakers, sends the purchase requests directly to Supply Service. This policy was implemented in April 1978 because Prosthetics Service involvement was considered too cumbersome and time-consuming.

Where Prosthetics Service is used, their actual involvement in the procurement process is limited. They do not determine the pacemaker source and are not normally involved in price determination. Normally, Prosthetics Service determines entitlement for prostheses; however, this determination usually does not take place until the pacemaker has already been implanted making this function meaningless. Since inpatients are entitled to prosthetic devices, and pacemaker implantation is an inpatient procedure, the patient is evidently entitled to receive a pacemaker upon admission. Prosthetics personnel usually maintain the fund control point for pacemakers and report pacemaker purchases on their AMIS Report segment.

Conclusion

The pacemaker ordering process used at the medical centers audited is time-consuming and does not follow normal procurement procedures. Supply and Prosthetics Services' participation in the requisition process is limited. The role of Supply Service needs to be expanded as discussed in Chapter 2. Prosthetics Services' current involvement results in processing delays without providing additional controls over the requisition process. The Department of Medicine and Surgery needs to clearly define the roles of the services involved in the requisition process, including the appropriateness of continued Prosthetics Service involvement.

RECOMMENDATION NO. 3:

That the Department of Medicine and Surgery define the roles of the services involved in the pacemaker requisition process, including a determination of continued Prosthetics Service involvement.

Receipt of Pacemakers

The pacemaker receipt process also varies among medical centers, ranging from delivery and routing through Supply, Prosthetics, and Surgical Services, to delivery by the sales representative directly to the surgical suite or Cardiology Service. Employees responsible for signing receiving reports do not always physically receive or inspect pacemakers upon delivery.

At the Wadsworth VA Medical Center, pacemakers are delivered directly to the operating room by the sales respresentative or a delivery service. Prosthetics Service is notified of delivery either by the operating room clerk, who forwards the packing or delivery slip, or by the sales representative. Based on this information, the Prosthetics personnel sign the receiving report as the using service and forward it to Supply Service. Prosthetics personnel do not physically receive the pacemakers prior to certifying receipt and are totally dependent on operating room personnel or the sales representative to provide accurate receiving information.

At the Hines VA Medical Center, pacemakers are normally received in the Supply warehouse and then delivered directly to Surgical Service. The operating room supervisor initials the receiving documents which are then taken to the Prosthetics Clerk who signs as having inspected and received the pacemakers.

Pacemakers at the Denver Medical Center are received by Supply Service and taken to Prosthetics Service. After prosthetics personnel sign for receipt, Supply Service considers them accountable. Prosthetics personnel have Escort Service deliver pacemakers to Surgical Service. Since prosthetics personnel do not obtain a signed receipt, they cannot prove that it actually has been delivered to Surgical Service when they claim that a pacemaker has not been received.

At the Portland VA Medical Center, pacemakers are delivered directly to the Cardiac Catheterization Laboratory. A lab technican calls the Prosthetics Clerk to notify her of the delivery. The Prosthetics Clerk, depending completely on the technician's statement that the pacemaker has been received, signs the receiving report as having received and inspected the pacemaker.

The Memphis and Brooklyn VA Medical Centers, which receive inventory on consignment, have pacemakers delivered directly to the operating room suite by sales representatives. After implanting one of the consigned pacemakers, Prosthetics and Supply Services process the paperwork to order the pacemaker and then immediately sign for its receipt although they have not seen it.

Because personnel sign for receipt of pacemakers that they have not actually received or inspected, the effectiveness of the control of pacemakers after delivery to the medical center is weakened. Since medical center staff that actually receive and use the pacemaker do not sign for them, they cannot be held accountable for "missing" pacemakers. This increases the VA's vulnerability to paying for items not actually received and to making duplicate payments.

The Department of Medicine and Surgery should establish and enforce controls over the pacemaker receipt process. Although delivery methods and using services may vary at different medical centers, personnel in the services which receive and use the pacemakers should be signing receiving reports upon which payments are based and held accountable for pacemakers delivered for their use.

RECOMMENDATION NO. 4:

That the Department of Medicine and Surgery establish and enforce criteria for the control of the pacemaker receipt process, including acknowledgement of receipt by the using service.

Pacemaker Inventories

All eight medical centers audited maintained inventories of pacemakers, either purchased or on consignment. There are no current agency or local criteria for determining appropriate inventory levels, or for establishing inventory controls. Additionally, inventory security is inadequate at some medical centers.

Personnel from Kaiser Permanente Medical Care Programs of Southern California stated that they do not stock pacemakers. They feel that maintaining an inventory is not appropriate due to frequent changes in technology, and because it is desirable to have the manufacturer test each pacemaker shortly before implant. Staff of the Surgeon General of the Department of the Army also indicated that they do not stock pacemakers due to battery life considerations and manufacturer quality control checks needed prior to implantation. All nine of the hospitals affiliated with VA Medical Centers maintain pacemaker inventories; five have stock on consignment and four purchase stock.

In May 1974, the Director, Supply Service on the advice of Surgical Service, directed medical centers that implantable pacemakers should not be stocked due to uncertain demand, lessening of useful life by stocking, and the creation of additional expenditures. As a result of a request from a medical center to stock pacemakers, the Director of Field Operations of Region 1 advised that the VA medical expert felt pacemakers should not be stocked anywhere under any circumstances, but it could be a local decision to stock an extra pacemaker in the using service.

In March 1975, VA Central Office Supply Service was notified that a surgeon at one medical center had signed an agreement with a pacemaker manufacturer which allowed the company to leave two pacemakers in Surgical Service to be readily available for implanting. If a unit was required, Surgical Service would request a pacemaker purchase and implant the pacemaker on hand. As a result of this information, VA Central Office Supply Service personnel contacted three medical centers and were told that two of the three were maintaining stock in basically the same manner. No action was taken to either issue guidelines on appropriate inventory methods and levels or to advise medical centers to discontinue these practices.

According to information requested by the Department of Medicine and Surgery in March 1979, there were 443 pacemakers in stock at 85 medical centers. This represented 14.6 percent of the 3,049 pacemakers reported as purchased in Fiscal Year 1978. Seven of these 85 medical centers had an average of two pacemakers on hand even though they had not purchased any pacemakers in Fiscal Year 1978. One station reported having at least half as many on hand as purchased in Fiscal Year 1978 and 24 stations reported having at least 25 percent of the number purchased in Fiscal Year 1978 currently in stock. The value of these 443 pacemakers in stock is approximately $900,000.

Physicians at the eight medical centers visited stated they must have pacemakers on hand so that implants are not delayed by the procurement process, or in case of pacemaker failure during implantation. However, the number of pacemakers in stock at some medical centers is not justified. Inventories of pacemakers range from 1 to 15 units, with up to 7 different brands and 10 different models. Seven of the medical centers have purchased their pacemaker inventory at a total cost of approximately $48,185. Inventory with expired shelf life was found at the Memphis and Denver VA Medical Centers, and inventory with shelf life that was about to expire was found at the Wadsworth VA Medical Center. Three medical centers had pacemakers which had been on the shelf for over four months.

The Brooklyn and Memphis VA Medical Centers maintain inventory on consignment. The employees of the Memphis VA Medical Center are not signing for receipt of pacemakers left on consignment, and their inventory is maintained by sales representatives. The operating room coordinator at the Brooklyn Medical Center signs a receipt for pacemakers left on consignment.

Inventory control records for pacemakers were not adequate at seven medical centers and physical security of pacemaker inventory was not adequate at two medical centers visited. The Philadelphia VA Medical Center stores pacemakers in an operating room suite closet which was observed open and unattended at least twice during the audit. Also, inventory records are not maintained at Philadelphia. Six pacemakers which had been purchased but were not implanted in veteran patients or in stock could not be accounted for by the audit team. Supply, fiscal, and professional staff could not locate or explain what happened to these missing pacemakers. At the request of Office of Investigation staff, the manufacturer reviewed its pacemaker registration records and furnished the following information. Three of the pacemakers were returned to the company, who issued credit memos to the Philadelphia VA Medical Center. Another pacemaker was implanted at the medical center; however, the pacemaker implant log does not reflect this. The manufacturer had no record of registration for the two remaining pacemakers. The two missing pacemakers were purchased at a total cost of $3,250.

The Portland VA Medical Center stores pacemakers and accessories in an unlocked cabinet in the Cardiac Catheterization Laboratory. The Wadsworth VA Medical Center had pacemakers in two different areas, one in Cardiology Section and two in the operating room suite. The pacemakers in the operating room were not in a locked cabinet. The remaining medical centers keep pacemaker inventories in operating room suites, some in locked rooms and others in areas that are unlocked at least part of the time. None of the medical centers maintain inventory records which control pacemakers from time of receipt until implantation.

Conclusion

The Department of Medicine and Surgery should review the pacemaker inventory practices currently in effect at VA Medical Centers. Guidelines should be developed for maintaining pacemaker inventories, taking into consideration pacemaker delivery time and pacemaker usage rates. If inventories continue to be maintained, medical center staff should periodically review and determine appropriate inventory levels and mix based on their local usage and needs.

The propriety of stocking pacemakers on consignment should also be reviewed. If this is an acceptable practice, medical centers should be advised of their responsibilities and liabilities.

Medical centers should also establish adequate inventory controls and records, and ensure proper security of pacemakers. Consolidated inventory records should be established to control pacemakers from delivery until implantation. Such records systems will help medical center officials monitor inventory levels, control shelf life expiration dates, calculate usage rates of various brands and models of pacemakers, and document release of pacemakers to authorized personnel. Physical security of pacemakers should be improved to limit access to authorized staff only, discourage pilferage, and ensure that pacemakers purchased by the VA are properly used.

RECOMMENDATION NO. 5:

A. That the Department of Medicine and Surgery determine under what circumstances medical centers should maintain pacemaker inventories, including the propriety of stocking pacemakers on consignment.

B. That, if pacemaker inventories are to be maintained, the Department of Medicine and Surgery establish criteria and direct medical centers to:

1. Establish pacemaker inventory control and records systems;
2. Ensure the security of pacemakers inventories; and,
3. Periodically review and adjust pacemaker inventory mix and levels based on local conditions and rates of usage.

Disposition of Removed Pacemakers

The medical centers audited do not have adequate controls to ensure that the VA receives all possible credits due for pacemakers removed from patients. Pacemaker manufacturers provide various types and amounts of credit for returned pacemakers. Normally, the manufacturers grant credits for defective pacemakers returned within certain warranty periods, and at least one company also provides credits for pacemakers which are not defective. Medical centers are not routinely returning pacemakers to the company, and physicians are not notifying the medical centers' Supply Services of pacemakers returned.

Physicians are not routing removed pacemakers to Supply Service for appropriate action. Physicians at seven medical centers are returning pacemakers, which may be defective and for which credit may be due, directly to the sales representatives without notifying Supply Service. Other pacemakers are thrown out or kept for display rather than returned to the manufacturer for testing and credit determination. Since Supply Service is not routinely notified of pacemakers given directly to sales representatives, the medical centers are dependent on the decision and action of the company to issue appropriate credit.

At the Philadelphia VA Medical Center, physicians send explanted pacemakers, thought to be defective, back to the manufacturer for credit if the pacemakers are believed to be within the warranty period. However, there are no written policies and procedures for this, and the physicians do not keep records of these transactions, resulting in their not knowing if credit is ever received. Currently, there are 13 explanted pacemakers in the operating room suite. One of these pacemakers was explanted eight months after it was implanted, which indicates some credit may have been due the VA at the time of explant.

At the Wadsworth VA Medical Center, the current procedure is for explanted units to be returned directly to sales representatives by Cardiology staff without being routed through Supply or Prosthetics Services. Medical Center staff rely on the company to test the pacemaker and determine if credit is due. No controls exist to ensure credit determinations are made for all pacemakers returned to the manufacturer. The most recent evidence of credits received for returned units was as a result of the 1977 Medtronic, Inc. recall. The medical center staff could only show that 17 of 23 units explanted because of this recall were returned by Cardiology through Supply Service. The VA received credits for four of these units. The company determined that credit was not due for 10 units, and there is no documented credit determination for the remaining units.

At the Denver VA Medical Center, the Surgical Service staff have also been dealing directly with the pacemaker companies. Some pacemakers have been exchanged between Surgical Service and the company without Supply Service's knowledge. A review of the pacemaker records on file in Surgical Service for Fiscal Year 1979 showed that 4 of 11 replaced pacemakers were probably still under warranty when removed. The possibility of partial credit was not explored by hospital staff for these pacemakers.

In addition to not ensuring that all possible credits are issued, two stations were not applying or collecting credits actually granted on pacemakers. At the Philadelphia VA Medical Center, supply personnel could not match credit memos with the applicable purchase orders so they sent them to Fiscal Service. Ten unapplied credit memos on pacemakers and related products were found in Fiscal Service. These credit memos totalled $9,625 and dated back to 1976. At the Hines Medical Center, supply personnel were holding two credit memos over six months old, totalling $3,590. This medical center has recently contacted pacemaker companies to determine if there were any other credits due. One company reported that they had issued eight other credits totalling $5,028, which the medical center had not applied to other purchases or collected.

Medical centers could reduce their pacemaker expenditures by establishing controls over the disposition of removed pacemakers to ensure that all credits due are received and applied. All pacemakers should either be turned in to Supply Service, or Supply

Service should be notified of all pacemakers turned over to sales representatives. Warranty information for pacemakers should be obtained and reviewed and credit requested whenever appropriate. A system to ensure that credits due are applied should be established.

RECOMMENDATION NO. 6:

That the Department of Medicine and Surgery establish and implement controls to ensure that medical centers request, receive, and apply all possible credits for pacemakers.

Chapter 4

PACEMAKER MONITORING

Background

In January 1976, the Acting Director of Medical Service, Department of Medicine and Surgery, requested approval to explore the possibility of developing appropriate contractual services to enable selected VA health care facilities to purchase pacemaker evaluation services. At that time, the VA had approximately 500 patients with pacemaker implants. Concerned with the potentials of pacemaker operating failures, the Department of Medicine and Surgery identified a need to follow VA patients with pacemaker implants. The Chief Medical Director approved the proposal to further explore the possibility for developing appropriate contractual agreements for pacemaker evaluation and establishing a register of VA pacemaker patients.

After reviewing this approval, the ACMD for Professional Services suggested that representatives of Medical Service and other appropriate services meet to determine what measures to take. These representatives formed a Pacemaker Committee and reported that the VA has absolute responsibility for lifelong surveillance of eligible pacemaker dependent veterans. This committee recommended that a circular be written establishing a pacemaker surveillance program and that appropriate guides or even a policy manual chapter be developed. Neither this circular nor guides has yet been published.

An agency pacemaker policy is currently under development by the Department of Medicine and Surgery.[3] Information on pacemaker purchases was gathered in March 1979 and meetings have been held to discuss monitoring of pacemaker patients. A registry of VA pacemaker patients is planned.

Monitoring by Other Health Care Organizations

The staff and administrations of the other hospitals contacted do not take the direct responsibility to assure that pacemaker patients receive follow-up monitoring. At each hospital, pacemaker monitoring was arranged between the patients and their physicians, rather than being the direct responsibility of the hospital where

[3] The Department of Medicine and Surgery issued Circular 10-79-269 on November 13, 1979. This circular is about cardiac pacemaker prostheses and addresses the development of surveillance plans.

the implant was performed. Seven of the nine hospitals affiliated with VA Medical Centers reported that both telephone and clinical monitoring of pacemakers is available.

Sample of VA Pacemaker Patients

As shown in Table C, our sample of Fiscal Year 1978 pacemaker implants included 424 patients. Of these patients, 32 have relocated from the patient service areas of the medical centers sampled, 71 are deceased, and 14 patients were excluded from the lists of those that may need VA pacemaker monitoring because their pacemaker has been removed or they are under a private physician's care. The medical records for the relocated patients have been transferred to other VA Medical Centers and follow-up monitoring was not verified. Of the 307 remaining patients who may need VA pacemaker monitoring, 48 patients (16 percent) have not been followed by the VA in the past year and medical center staff do not know whether these patients are followed elsewhere.

TABLE C

CURRENT MONITORING OF SAMPLE PATIENTS WITH FY 1978 PACEMAKER IMPLANTS

	Denver	Portland	Tampa	Philadelphia	Memphis	Hines	Wadsworth	Minneapolis	Total
A. Sample Patients	34	63	36	49	29	50	82	81	424
B. Exclusions:									
Relocated	12	4	2	-	2	1	5	6	32
Deceased	3	19	6	7	7	7	12	10	71
Other [1]	1	1	1	2	0	4	1	4	14
C. Net Sample - Patients requiring followup.	18	39	27	40	20	38	64	61	307
D. Patients monitored in last six months of those requiring followup.	6(33%)	37(95%)	27(100%)	22(55%)	15(75%)	36(95%)	48(75%)	48(79%)	239(78%)
E. Patients not monitored in last six months. [2]	8	0	0	2	0	0	3	7	20
F. Patients not monitored in past year. [2]	4	2	0	16	5	2	13	6	48

[1] Patients who have had the permanent pacemaker removed or who have been released to the care of private physicians.

[2] Lines E and F are exclusive of each other.

Responsibility For Pacemaker Monitoring

Attitudes toward the VA's responsibilities for monitoring pacemakers vary. The Department of Medicine and Surgery has not defined the responsibility or liability of the VA in this area.[4] The medical centers audited do not monitor all VA patients following implant and if a patient misses scheduled appointments, they do not routinely try to determine the cause.

At the Memphis VA Medical Center, the staff state they do not attempt to comprehensively follow pacemaker patients. The Acting Chief of Staff feels that it is desirable to follow patients who have catastrophic medical problems and the VA's followup efforts should not be restricted to pacemaker patients. He believes that this apparent new interest in pacemaker policies is contrary to policies on reducing outpatient clinical costs.

Methods of Monitoring

The medical centers audited are using different methods to monitor pacemaker patients, as shown in Table D. All eight medical centers use clinical monitoring. Seven of the eight medical centers are also using telephonic monitoring to varying degrees. Attitudes towards the necessity and usefulness of telephonic monitoring vary among cardiologists. According to the comments received from the Chief Medical Director, attitudes concerning telephone monitoring also vary considerably among non-VA cardiologists.

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[4] The Department of Medicine and Surgery issued Circular 10-79-269 on November 13, 1979. This circular states that all veterans who have received cardiac pacemaker prostheses must have adequate follow-up surveillance and that it will be provided under VA auspices if appropriate or by referral to another acceptable health care provider.

TABLE D

METHODS OF PACEMAKER MONITORING USED

VA Medical Centers	Monitoring Methods Used		
	VA Clinic	Telephone VA In-House	Telephone Private
Denver	Yes	No	No
Portland	Yes	No	Cardio-Pace
Tampa	Yes	Yes	No
Philadelphia	Yes	No	Anthropromedics [1]
Memphis	Yes	No	Pacemaker Diagnostic and Intermedics
Hines	Yes	Yes	No
Wadsworth	Yes	Yes	No
Minneapolis	Yes	Yes	No
Total (8)	8	4	3

[1] Philadelphia VA Medical Center does not normally use telephonic monitoring, but is currently evaluating Anthropromedics telephonic monitoring system for the VA Marketing Center.

At the Denver VA Medical Center, the cardiologist uses clinical monitoring exclusively. He stated that telephone monitoring is not cost effective since pacemaker patients must be examined physically for the underlying condition for which the pacemaker was prescribed. The Philadelphia Medical Center does not normally use telephone monitoring service; but now has ten patients monitored telephonically in conjuction with the VA Marketing Center's evaluation of Anthropromedics monitoring service. Patients with the ten oldest pacemakers were selected for telephonic monitoring.

Four of the medical centers use in-house telephonic monitoring systems. The Hines VA Medical Center tries to monitor all their pacemaker patients telephonically. The Wadsworth, Minneapolis, and Tampa Medical Centers monitor from 20 to 69 percent of their pacemaker patients telephonically. Three of the medical centers are using outside-VA monitoring services. The Portland VA Medical Center has its pacemaker patients monitored telephonically through a local contractor, Cardio-Pace, Inc.

Criteria for selecting patients for telephonic monitoring include: availability of transmitting equipment, ability of patients to use the telephone transmitter and to follow a monitoring schedule, and the patient's difficulty in attending a clinic due to distance or disability. Some medical centers call the patients, while others depend on the patients to call the medical center when scheduled. At medical centers utilizing telephonic monitoring, physicians stated that the number of outpatient clinic visits needed to monitor pacemaker performance is reduced by using telephone monitoring.

The Memphis VA Medical Center monitors 60 patients. Twenty-four of these patients are monitored "free" by Intermedic, Inc. with the purchase of their pacemaker. The medical and surgical staff consistently stated that no criteria exist to select the means by which patients are monitored, or to determine the interval between episodes of monitoring. Recently Pacemaker Diagnostic Clinic of America, Inc. independently initiated telephonic monitoring of 33 patients, 11 of which also receive telephonic monitoring by Intermedic, Inc. Of these 11 patients, two are also routinely seen in cardiovascular clinic for pacemaker monitoring.

Frequency of Monitoring

The frequency of pacemaker monitoring depends upon the method of monitoring used and varies with each medical center. The Department of Medicine and Surgery has not issued any guidelines on the suggested frequency of monitoring pacemaker patients.[5] Two of the medical centers have written monitoring policies, five have informal policies, and the Memphis VA Medical Center does not have any policy on monitoring patients.

At the four medical centers with in-house telephone monitoring equipment, patients are either monitored monthly or the monitoring intervals vary with each individual patient. The Memphis VA Medical Center does not have a schedule for its monitoring services. The Portland VA Medical Center telephone monitoring contract provides for bi-monthly monitoring during the first 24 months after implant, monthly from 25 to 36 months after implant, and bi-monthly thereafter.

Three medical centers schedule clinical pacemaker monitoring at three month intervals. At the Wadsworth VA Medical Center, patients are seen monthly for the first six months and then every three months. With regular telephonic monitoring, some patients at the Portland VA Medical Center are seen in the pacemaker clinic as infrequently as once a year.

Conclusion

The Department of Medicine and Surgery has not published specific guidelines on monitoring pacemaker patients. Individual medical centers have established their own understanding of VA responsibility for VA patients with pacemaker implants, developed their own means for monitoring pacemakers, and determined the appropriate frequency of followup. As a result, pacemaker monitoring is not provided for all VA pacemaker patients, and the method and frequency is inconsistent throughout the agency.

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[5] The Department of Medicine and Surgery issued Circular 10-79-269 on November 13, 1979. This circular addresses surveillance plans.

Until the Department of Medicine and Surgery clearly defines the responsibilities for monitoring pacemaker patients, the service provided to VA patients will continue to be inconsistent within the VA system. If it is determined that telephonic monitoring is appropriate and cost effective, guidelines on its use should be developed and issued.

RECOMMENDATION NO. 7:

That the Department of Medicine and Surgery:

a. Define the VA's responsibility for pacemaker patients;

b. Determine the appropriate method of monitoring pacemakers; and,

c. Establish guidelines for determining the appropriate frequency of pacemaker monitoring.

Maintaining Pacemaker Records

Six of the seven medical centers which use telephonic monitoring file clinical monitoring results but not telephonic monitoring information in the patients' medical records. Medical center staff responsible for monitoring patients keep some pacemaker patient records separate from the patients' permanent medical records. Information maintained in these separate records varied among medical centers. Some cardiologists keep pacemaker model and serial number information and clinical information separate, while others forwarded this information to the medical record. If a medical record is requested by another VA Medical Center, the separate pacemaker information may not be forwarded. At the Tampa VA Medical Center, a patient's medical record was transferred to the West Haven VA Medical Center. The separate pacemaker records, containing information on pacemaker functioning and EKG printouts, was still in Tampa's EKG clinic four months later. The cardiology staff considered the patient lost to followup.

The Department of Medicine and Surgery does not normally allow the maintenance of patient information that is not included in the medical record. If these pacemaker records are an exception, this information should be communicated to the medical centers.[6] If this information is required in the medical records, this fact should be clarified.

RECOMMENDATION NO. 8:

That the Department of Medicine and Surgery determine if separate pacemaker records should be maintained and clarify what pacemaker information should be in the patient's medical record.

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[6] The Department of Medicine and Surgery issued a circular on November 13, 1979 which addresses the maintenance of patient information.

Chapter 5

PACEMAKER RECALLS

The VA has not established adequate record systems or procedures to protect pacemaker patients affected by pacemaker recalls.[7] The Department of Medicine and Surgery has not provided specific guidelines on maintaining pacemaker records or on processing pacemaker recalls.[8] The audit showed that model and serial numbers of recalled pacemakers cannot always be readily traced to the appropriate patient; medical centers have not developed or are not using an organized procedure to communicate recall information to all appropriate staff; and, medical center personnel are not reporting locally identified defective pacemakers to the VA Marketing Center.

Background

The Department of Medicine and Surgery established a policy in May 1978 for removing hazardous medical devices and for notifying appropriate authorities of hazardous products identified at VA facilities. VA Central Office Supply Service staff stated that pacemakers are covered by this general recall policy. This policy states that it is the medical center's responsibility to initiate an organized procedure to communicate the necessary recall information to all appropriate staff. It alerts medical center health care professional staff and administrators that they risk increased liability should a patient be injured by a defective device which the facility had been warned of, but did not remove from service. This policy states, "The facility can no longer use the defense that they were not aware of a product recall or have not received appropriate notice from the manufacturer or vendor." This policy requires medical centers to establish procedures to identify medical devices used which are affected by the recall, and to take necessary corrective action. The policy also requires medical centers to inform the VA Marketing Center of locally identified medical device malfunctions so other medical centers and the Food and Drug Administration can be alerted.

[7] The Department of Medicine and Surgery issued Circular 10-79-268 on November 6, 1979. This circular establishes a cardiac prostheses registry at each medical center and a central registry at VA Central Office.

[8] The Department of Medicine and Surgery issued a circular on November 13, 1979 which addresses the maintenance of pacemaker records and issued a letter on November 7, 1979 which address recalls on potentially hazardous products, including pacemakers.

Pacemaker manufacturers have recalled approximately 110,000 pacemakers since 1972. Recall notices have recommended returning all existing stock and either monitoring implanted pacemakers more frequently or replacing implanted pacemakers. The recall by Medtronic, Inc. in 1977 resulted in the replacement of pacemakers for 451 patients at 69 VA Medical Centers.

Communicating Recall Information

The communication of pacemaker recall information to the medical centers, as well as within the medical centers, is inadequate. This has resulted in an ineffective system for screening patients possibly affected by recalls.

The VA Marketing Center reviews Food and Drug Administration Enforcement Reports and information provided through the Food and Drug Administration's Device Experience Network. If pacemaker recalls are included in this information, the Marketing Center calls the pacemaker manufacturers to determine if any recalled pacemakers had been purchased by VA Medical Centers, and if those medical centers have been notified. The Marketing Center or VA Central Office do not routinely notify medical centers of all pacemaker recalls. Instead, the VA relies on the manufacturer to identify the patients affected and to notify affected medical centers directly.

The VA Central Office policy on medical device recalls requires that medical centers subscribe to and review the Food and Drug Administration Enforcement Reports. These reports do not always identify the specific serial numbers included in the recall. More specific information including serial numbers, should be obtained through VA sources; however, the VA Marketing Center does not always obtain and distribute information on specific serial numbers.

The Food and Drug Administration Enforcement Reports listing pacemaker recalls are also not always routed to either the implanting or monitoring physician at VA Medical Centers. Normally, these reports are received and reviewed by the medical center's Supply Service to determine whether any items listed are in stock. Since pacemaker inventories are not controlled by Supply Service, pacemaker recall information must be forwarded to the appropriate professional staff for review. However, physicians at seven of the medical centers are not routinely notified of pacemaker recalls through VA channels. The Portland VA Medical Center does not have a policy or procedure on recalls. Pacemaker information in the Food and Drug Administration Enforcement Reports is also not forwarded to the professional staff at six other medical centers as required by the agency medical device recall policy. Instead, the physicians rely on the manufacturers to provide recall information. The manufacturers' information on specific patients affected is based on patient registrations submitted to them by the implanting medical center at the time of implant. If a patient is monitored by a medical center other than where the implant was performed, the manufacturers' information would not be received by the medical center monitoring the patient. Additionally, the medical center where the implant was done may not know where the patient is currently being monitored. As a result, the VA must establish additional procedures to effectively disseminate recall information.

An example of some of the problems with communicating recall information occurred at the James A. Haley Veterans' Hospital during the recent American Technology, Inc. recall. The Cardiothoracic surgeon was notified of the recall by a letter from the manufacturer; however, action taken was limited based on oral statements by the sales representative. The medical center received information on this recall from the Food and Drug Administration Enforcement Report and a special teletype from the VA Marketing Center; however, this information was not promptly forwarded to the physician responsible for monitoring pacemaker patients.

An August 9, 1979, letter from American Technology Inc. notified the Chief, Cardio-Thoracic Surgery that a series of two pacemakers models used by the medical center, "exhibited an unsatisfactory failure rate." The letter "recommends that the patients under your care, and in particular pacemaker dependent patients, be monitored closely." A salesman for the company also advised the surgeon orally that the warning applied only to pacemakers implanted within the past 18 months. This 18 month limitation was not based on any documentation. As a result, the surgeon replaced two pacemakers in VA patients and initiated closer monitoring of two other patients who had implants in the past 18 months only.

The Food and Drug Administration Enforcement Report on this recall, dated August 29, 1979, was routinely received and filed away by Pharmacy Service without action or significant notice. On September 7, 1979, the Director's office received a teletype message on the recall from the VA Marketing Center. An action copy of the teletype was sent to Supply Service. The teletype stated that the affected pacemakers:

> ... are considered adulterated and misbranded in that they have exhibited an unsatisfactory significantly high rate of premature failure. Premature failures of these pacemakers can and has resulted in incidents requiring explantation of pacemakers implanted in patients due to decreased pulse generation, and in some incidents complete cessation of pulse generation, of the pacer. This situation presents a potentially serious health hazard to patients who are life-dependent on the proper functioning of the pacemaker, with potentially adverse consequences occurring of an immediate life-threatening nature.

The audit team determined that as of September 13, 1979, Supply Service was aware of this teletype message but had not informed the professional staff.

Identifying Patients Affected by Recalls

Medical centers do not always maintain consolidated records on each patient's pacemaker model and series but rely on the manufacturers to identify patients affected by a recall. However there is no guarantee that information provided is complete. The James A. Haley Veterans' Hospital did not have consolidated records on pacemaker models and serial numbers of pacemakers implanted in patients under its care. The audit team's development of this information required reference to several unrelated and incomplete sources. Despite this effort, serial numbers for several implanted pacemakers could not be determined. In addition to the 4 patients which the surgeon thought were affected by this recall, the audit team identified another 12 pacemakers possibly affected by the recall. Of these 16 patients identified, 1 patient is deceased, 2 have had the pacemakers replaced, and 2 have been notified of the need for closer monitoring. No action was taken for the remaining 11 patients. The brand recalled has been used by this medical center since at least May 1977, and the recall affected pacemakers manufactured prior to May 25, 1977. Since the audit sample did not include patients who received implants prior to October 1977, additional VA patients may have pacemakers affected by this recall.

The problem of tracing recalled pacemakers to the affected patient was also found at other medical centers. For example, at the Denver VA Medical Center, a pacemaker implant log was not started until Fiscal Year 1979. A review of this log shows that information needed to identify patients affected by recall is incomplete. The only other means of identifying a brand, model and serial number for a particular patient was to review each patient's medical record.

Cardiologists at the Wadsworth Medical Center depend almost completely on information provided by the manufacturer on pacemaker recalls. Action is taken when patients names are referred by the manufacturer. The medical center has no concise list of patients, pacemaker models and serial numbers which can be quickly reviewed when Supply Service notifies them of recall information.

The Portland Medical Center also relies on recall information provided by the manufacturer; however, model and serial number information can be retrieved from the contract monitoring service's computerized patient data bank.

Communicating Internally Identified Hazards

In addition to not communicating hazards identified by the Food and Drug Administration, medical centers are not communicating information on internally identified defective pacemakers. According to current Department of Medicine and Surgery policy, the Chief of Supply Service is to be notified and findings reported to the Test and Evaluation Staff at the VA Marketing Center when a VA Medical Center identifies a potential hazard. None of the medical centers visited had reported internally identified defective pacemakers to the VA Marketing Center.

From 1976 to the summer of 1978, physicians at the Hines VA Medical Center noticed that Medtronic, Inc. Model 5590, Group II, pacemakers were failing prematurely. Physicians at Hines VA Medical Center participate with other local health care providers to pool information on pacemakers through the Interinstitutional Cardiovascular Center's Cardiac Pacemaker Registry. This registry detected a pattern of failures of the Group II Xytron pacemakers. The Food and Drug Administration reported to this group that similar failures had been reported.

Medtronic, Inc. made a major recall of all the Group I, model 5950, pacemakers but Group II pacemakers were not included in the recall. The medical center contacted Medtronic, Inc. but the manufacturer did not issue an advisory on the Group II. If the patients were pacemaker dependent, the manufacturer suggested the physicians use their clinical judgement in deciding whether they should replace these pacemakers which could fail suddenly without any warning. Medtronic, Inc. offered to provide the Hines VA Medical Center with a pacemaker inhibitor to detect which patients were totally dependent on their pacemakers. The VA physicians decided they would remove pacemakers in the dependent patients. In a memorandum to the Chief of Staff in March 1979, the cardiologist stated:

> Although Medtronics refused to call this Group II xytron series an advisory, there are more and more failures, sudden failures that are occurring with this unit. Medtronics suggests explantation of all these units in pacemaker dependent patients, not just for our hospital but for other hospitals in the United States.

This information was not submitted to the VA Marketing Center or distributed to other VA Medical Centers.

Conclusion

The VA is not adequately communicating all pacemaker recall information to the appropriate professional staff, not maintaining record systems to trace recalled pacemakers to the affected patients, and not communicating information on internally identified defective units to all medical centers. As a result, the VA is not adequately protecting patients affected by pacemaker recalls leaving the VA potentially liable for inadequate or improperly documented recall actions.

RECOMMENDATION NO. 9:

That the Department of Medicine and Surgery ensure that:

a. All pacemaker recall information is communicated to the appropriate professional staff;

b. The serial numbers of pacemakers can be readily traced to the appropriate patient; and,

c. Information on internally identified defective pacemakers is communicated to the office responsible for analyzing and distributing such information.

Chapter 6

ACQUISITION OF PACEMAKER MONITORING CAPABILITIES

Background

Since 1973 the VA Marketing Center has tested seven pacemaker evaluation systems and reported that five were acceptable. As of September 1975, two companies, Cardiac Datacorp, Inc. and A. L. Stanley and Associates had received acceptable ratings. At that time, the Director, Medical Service, asked the Director, Supply Service if it would be possible to contract for pacemaker evaluation services. Three possible providers of the service were suggested: Cardia Datacorp, Inc., Pacemaker Diagnostic Clinic of America, Inc.; and Wyeth Laboratories. The Director, Supply Service, requested an outline of services expected so that contract specifications could be developed. There is no evidence of any further action taken at that time.

Evaluations were completed and acceptable ratings were given to ESB Medcor, Inc. in November 1977 and to Cardiocare Testing Corporation in May 1978. In June 1978, Pacemaker Diagnostic Clinic of America, Inc. formally requested an evaluation by the VA Marketing Center. The results of this evaluation were published in February 1979 with the service provided described as excellent.

In December 1978, the VA Marketing Center provided information on the evaluation, summaries, service, and cost for Pacemaker Diagnostic Clinic of America, Inc. and Cardiocare Testing Corporation to the Director, Medical Service. At that time, they also notified VA Central Office that Cardiocare Testing Corporation had been purchased by VA's largest pacemaker supplier. VA Central Office personnel recommended against contracting for monitoring services with a subsidiary of a pacemaker manufacturer since it could result in a potential conflict of interest.

In February 1979, a representative of VA Central Office Medical Service recommended that VA Marketing Center establish a decentralized contract with Pacemaker Diagnostic Clinic of America, Inc. The contract was to include services to individual veterans recommended for surveillance by the treating hospitals plus a provision to allow the VA to benefit from information obtained on defective pacemakers. The Medical Service representative indicated that the VA was interested in a comparison of the merits and cost effectiveness of an in-house program with the commercial service.

If a contract was awarded, the VA would provide the company with full information on a planned internal study and solicit their cooperation with the comparison study.

There is no indication that the free monitoring services and/or equipment provided with some pacemakers was considered prior to contract development, that VA Medical Centers were consulted on their need for this type of monitoring service, or that a cost/benefits analysis or a comparison with VA in-house capability was performed. The Deputy for Program Management, Department of Medicine and Surgery, stated that one of the purposes of this contract was to measure in-house capabilities against contractual services.

Current Monitoring Contracts

A decentralized contract, effective July 1, 1979, was awarded to Pacemaker Diagnostic Clinic of America, Inc. on May 11, 1979. The contract states that it will be used by VA activities as a primary source of supply. The estimated requirements clause of the contract states no guarantee is given that any quantities will be purchased; however, the award information shows an estimated awarded amount of $400,000 for the contract period.

The company provides two types of telephonic monitoring: a rate and EKG printout at a cost of $25 per call and a waveform analysis at a cost of $32.50 per call. The firm requires a minimum of six pacemaker tests per patient during a twelve month period.

Attitudes toward telephone monitoring by Pacemaker Diagnostic Clinic of America, Inc. varied among medical centers. A cardiologist at Denver believes that any type of telephonic monitoring is not cost effective or needed since the patient must usually be seen clinically every three to four months. A cardiologist at Philadelphia believes that the decentralized contract is too expensive but a more cost effective telephone monitoring service could be used. A cardiologist at Hines indicated that use of this company's service would not be cost effective for a large hospital, and that telephonic monitoring could be accomplished internally at a third of the cost. The cardiologist at Wadsworth VA Medical Center is willing to use the company's service if mandated. He felt, however, that the cost is excessive when compared with Wadsworth's in-house telephonic monitoring which is currently in use. The cardiologist at Minneapolis thinks the service provided by Pacemaker Diagnostic Clinic of America, Inc. is quite expensive and stated that even hiring another technician and continuing to monitor in-house would still be cheaper. Tampa was one of the medical centers that originally tested this service and originally reported that they "would definitely recommend the system." The cardiologists now state, however, that the sales representatives are excessively pushy and aggressive and they were not generally impressed with the services from this company. Medical center staff stated that Pacemaker Diagnostic Clinic of America, Inc. sales representatives obtained names and addresses of pacemaker patients at the Memphis VA Medical Center by indicating to the staff that Central Office had authorized disclosure. The sales representatives contacted patients and furnished them transmitters. Schedules were set up to call patients weekly although a formal purchase order had not been authorized through the medical center's Supply Service.

Types of Telephonic Monitoring

One VA Medical Center has used a private telephone monitoring service since about 1975. The current cost of this service is a fixed fee of $10,520 per year, regardless of the number of phone monitorings accomplished. Based on the number of monitorings performed, the average cost per call is $7.80. This compares favorably to Pacemaker Diagnostic Clinic of America's cost per call of $25 for a similar service.

The monitoring service calls patients on a regular schedule. The patient's heart rate is analyzed immediately, and a written report is forwarded to the VA. The Medical Center's Cardiology Service is notified immediately by phone if a problem is detected so that necessary action can be taken. Patients may also call the monitoring service if they feel a problem exists. The company maintains computerized patient records with a history and the results of all telephonic transmissions. In the event that a patient misses a scheduled transmission, the company, after phone and written followup attempts to contact the patient, will call the VA Medical Center's Cardiology Service to try and locate the patient.

The other telephonic monitoring service identified at the VA Medical Centers visited was with Intermedics, Inc. which is free with pacemaker purchases. Also, the VA has in-house capabilities at the Tampa and Minneapolis Medical Centers. The VA Medical Center at San Francisco operates a district monitoring service for over 300 patients. According to their August 1979 proposal, they are willing to monitor patients from any larger area, including the nation. They indicate that the service would be equal to or better than the service offered by private firms and would probably be about 50 percent cheaper than private firms. They proposed a pilot program to encompass three to five states and estimate an annual cost of between $72 and $97 per patient. The Richmond VA Medical Center has proposed a district monitoring service. Their estimated annual cost is $44,441 for monitoring 265 pacemaker patients at an average annual cost of $168 per patient. Cost benefit information required by the Office of Management and

Budget has not been developed for the Richmond district proposal or the San Francisco pilot program.

The Department of Medicine and Surgery should determine whether telephonic monitoring is necessary and define when it is a viable alternative to clinical monitoring. If telephonic monitoring is recommended, consideration should be given to all possible alternatives for its acquisition. The service provided and costs should be considered for using or acquiring VA capabilities along with the costs and variety of services provided by private contractors.

RECOMMENDATION NO. 10:

That the Department of Medicine and Surgery determine if telephonic monitoring should be used and acquire it in the most beneficial and economical method possible.

Senator Stone. These hearings are to find out the VA policy and if it is now operative. The information presented will assist the VA in the continued development and implementation of a pacemaker acquisition and surveillance operation that will be second to none. One objective of this hearing is to provide the VA with state-of-the-art information and recommendations that can be used in the creation of a model pacemaker surveillance program. I want to thank the VA and the Food and Drug Administration and, particularly, the eminent doctors who have come here at their own expense to help us find out the right situation, and what action to take.

And I want to thank the VA for ordering the Inspector General's report to be used in this oversight hearing in a spirit of cooperation to assure veterans with cardiac pacemakers that the quality of their care will not vary based on regional residence; that they get high-quality service whether they reside in California, Maine, Mississippi, or Florida, according to the commitment that the country has made.

Now we will call our first witness, but first, may I ask Senator Stafford if he has a statement.

Senator Stafford. Thank you very much, Mr. Chairman. I do have a brief statement.

Oversight is an important responsibility of the Senate Committee on Veterans' Affairs. It is appropriate that, today, we review questions which have been raised concerning the Veterans' Administration's cardiac pacemaker program.

The Veterans' Administration has been a leader in its pacemaker program and this committee must encourage the Veterans' Administration to continue to develop and improve its program.

We are looking forward to hearing and, to the extent we cannot hear, the reading of today's testimony, including a discussion of the value of a pacemaker registry, the experience of other countries in the use and reuse of pacemakers, and the problems and limitations relating to pacemakers.

Pacemakers have been of great value to many who have needed such assistance. Our Nation's veterans have been the recipients of a beneficial program which members of this committee want to see grow and progress.

Mr. Chairman, I ask unanimous consent that, immediately following the statement I have just made, that that of Senator Strom Thurmond, a member of this committee, appear in the record.

Senator Stone. Without objection, it will be included.

[The prepared statement of Senator Strom Thurmond, a member of the Senate Committee on Veterans' Affairs, follows:]

PREPARED STATEMENT OF HON. STROM THURMOND, A U.S. SENATOR FROM THE STATE OF SOUTH CAROLINA

Mr. Chairman, it is a pleasure to be here this morning to receive testimony concerning the cardiac pacemaker program administered by the Veterans' Administration.

The first cardiac pacemaker was implanted in a patient in 1958, and since that time, the VA has participated in the development of this field of medical care. For example, the first nuclear-powered pacemaker implant that occurred in the United States was conducted at a VA medical center.

Mr. Chairman, since the VA started its program of pacemaker implants, the state-of-the-art has grown tremendously. The useful life of a pacemaker has been extended from a few months to fifteen years. The mercury-zinc powered pacemakers have been replaced by lithium alloy and nuclear power. Yet, the advent of this new technology has not eliminated the possibility of human mistakes, mechanical failures, progressive heart disease, and other adverse effects.

Thus this oversight hearing is very timely, and it is a continuation of this Committee's commitment to insure that our Nation's veterans receive the best possible health care.

Mr. Chairman, we have a distinguished list of witnesses today and I look forward to their testimony regarding the cardiac pacemaker implant program within the VA.

Senator Stone. We will now call our first witness, and at this point, I am going to make a change in the order of the printed witness list.

I will ask Mr. John Williams, the Deputy Inspector General of the VA, to come up for a few questions. He does not have a prepared statement, but I do want to ask him a few questions about the Inspector General's February 13, 1980, report and audit.

Mr. Williams, thank you very much for coming this morning. Do you have any remarks you would like to make before I ask a few questions?

Mr. Williams. No, sir. I only found out this morning that I was going to be here, so I have no prepared remarks at all. I am at your disposal.

Senator Stone. Mr. Williams, if you would look at your copy of the Inspector General's audit report, my first question is how did your report rate the VA protection of veterans who may have defective pacemakers?

Mr. Williams. How did we rate the protection?

Senator Stone. That is right. How did you describe the VA protection of veterans who might be walking around wearing a defective pacemaker?

Mr. Williams. You would find it right in the report, but we had some recommendations for improvement in the control in locating and keeping tabs on these veterans that were wearing them.

Senator **Stone**. I was referring to the statement in the audit report that there are inadequate procedures and records to protect the patients. Was that not one of your findings?

Mr. **Williams**. Yes, sir.

Senator **Stone**. Second, what details can you give the Committee about the VA's internal communication or warnings of defective pacemakers coming from the Food and Drug Administration or the manufacturer? In other words, recall information.

Mr. **Williams**. Well, we found, at the time of the audit—and I think I should point out, Mr. Chairman, that this audit was completed in September of last year.

At the time of the audit, I believe we found that controls were inadequate to really inform everybody that should know.

Senator **Stone**. Based on your findings at that time, could a veteran with a pacemaker receive consistent monitoring protection no matter where he or she is in the country?

Mr. **Williams**. At that time, no, sir, I don't believe so.

Senator **Stone**. What were your findings regarding prices that the VA pays for its pacemakers and what is the total annual cost of pacemakers?

Mr. **Williams**. We found that the prices varied extremely.

Senator **Stone**. A wide range of prices?

Mr. **Williams**. Yes, sir.

Senator **Stone**. Could competitive bids lower and stabilize these prices?

Mr. **Williams**. Yes, sir, in our opinion, it could. And that was one of our observations, I believe.

Senator **Stone**. And did you not find that, in one hospital which used competitive bids, the prices were 7 percent to 40 percent lower than they were elsewhere?

Mr. **Williams**. Yes, sir.

Senator **Stone**. Now, with regard to inventory control procedures by the VA, were they adequate at the time of the report?

Mr. **Williams**. No, sir, they were not.

Senator **Stone**. Did you find inventories with expired shelf life at two medical centers?

Mr. **Williams**. Yes, sir.

Senator **Stone**. Did you find that one VA medical center was removing pacemakers from dead patients and reusing them, and did you find this to be an authorized practice for all medical centers?

Mr. **Williams**. We did find that one medical center was reimplanting, and I believe we found that the policy was rather confusing on whether this was proper or not.

Senator **Stone**. At this time I ask that you accompany the VA witnesses when they testify toward the end of the session. Your office made a number of recommendations for improving the management of the VA's pacemaker program.

Do you know if those recommendations have been followed?

Mr. **Williams**. Yes, sir. Let me qualify that. I think action has been started on all of our recommendations. There have been policy statements issued by the Chief Medical Director, including this reimplantation.

And from what we see, the actions started will comply with the recommendations we made in our report.

Senator STONE. Thank you so much for this brief appearance to set the issues in place for discussion during this session.

I appreciate very much your willingness to come up and talk with us, thank you, sir.

Mr. WILLIAMS. You are welcome, sir.

Senator STONE. Our first panel of witnesses includes Dr. Bruce Innes, the director of cardiovascular surgery at the University Hospital of Jacksonville, Fla.; Dr. James J. Morris, Jr., Department of Medicine, Duke University Medical Center, Durham, N.C.; Dr. Victor Parsonnet, director of surgery, Newark Beth Israel Medical Center, Newark, N.J.; and Dr. Joseph W. Rubin, associate professor of surgery, Section of Thoracic and Cardiac Surgery, Medical College of Georgia, Augusta, Ga.

I thank these doctors for coming and making themselves available to help this committee. We really appreciate it.

Doctors, thank you so much. Whoever wishes to may proceed first.

A PANEL CONSISTING OF: DR. JOSEPH W. RUBIN, ASSOCIATE PROFESSOR OF SURGERY, SECTION OF THORACIC AND CARDIAC SURGERY, MEDICAL COLLEGE OF AUGUSTA, GA.; DR. BRUCE INNES, DIRECTOR OF CARDIOVASCULAR SURGERY, UNIVERSITY HOSPITAL, JACKSONVILLE, FLA.; DR. JAMES J. MORRIS, JR., DEPARTMENT OF MEDICINE, DUKE UNIVERSITY MEDICAL CENTER, DURHAM, N.C.; AND DR. VICTOR PARSONNET, DIRECTOR OF SURGERY, NEWARK BETH ISRAEL MEDICAL CENTER, NEWARK, N.J.

Dr. RUBIN. I presume you have availed yourself of the provided testimony.

Senator STONE. Yes, and the formal statements will be included in the record.

Dr. RUBIN. Senators, ladies and gentlemen, we discovered our followup deficiencies 7 years ago and, with respect to our VA center, attempted to communicate these deficiencies to our VA center.

Unfortunately, we received very little attention from administrative personnel within the VA and, as a result of our pilot studies into pacemaker followup, we undertook the followup of veterans on our own.

I believe that, as far as we are concerned, the IG's report is inaccurate with respect to records and management of recall since we do have a registry of our patients and, to the best of our knowledge, it is an up-to-date registry.

Unfortunately, the Inspector General's investigation of procurement and monitoring pacemakers in VA Center, Augusta, has had a detrimental impact upon the care of veterans with pacemakers in our area.

Subsequent to the investigation, the Medical College of Georgia, Pacemaker Surveillance Clinic, was prohibited from continuing valuable followup services to veterans that comprised about one-fourth of our total registry.

Restrictive administrative policies were set without a moment's consultation with us, despite our known and established experience with pacemaker therapy and monitoring in our medical district.

In our considered opinion, comprehensive pacemaker followup includes monitoring pacemaker function and cardiac rhythm, as well as the general assessment of the patient's other known conditions.

Responsibilities of implanting and prescribing physicians include followup care and accurate onsite patient data management.

Delegation of followup to other outside resources can only be accomplished ethically at the direct request of the patient. Mandatory surveillance, extramural to our present system, would seriously undermine operating patient care patterns within the medical center.

Designation of a specific extramural technical service in the absence of an operational surveillance clinic within the VA Center, Augusta, was prejudicial and demeaned the exemplary record of patient care that was offered by our telephone clinic.

We have found telephone monitoring to be an improvement over reliance upon referring primary physicians not completely familiar with all facets of pacemaker treatment.

Since beginning telephone monitoring 4 years ago—and I might point out at this time, in the previously provided testimony, our investigation into surveillance began 7 years ago, in late 1973—we have detected a decrease in postimplantation mortality risk, fewer hospitalizations for premature generator replacement and suspected system malfunctions.

More frequent contact scheduled according to patient needs has permitted early detection of serious malfunction, maximizes generator longevity, decreases operations and, above all, gives most patients an increased sense of security, especially those suffering from other serious illnesses.

This mechanism of care is least disrupting of day-to-day life and, by minimizing hospitalizations, alone, even outpatient hospitalizations, becomes cost effective.

Long-term care is not a requirement peculiar to pacemaker recipients. It is only commonplace that the prescribing physician pursue his responsibility unless the patient wills otherwise.

The Veterans' Administration may correctly remind us of our duties to patients through circular or policy statement, but uniform regulations of pacemaker followup will only confine those who are regulated.

Telephone monitoring is highly suited to our patient population which is spread out over Georgia and South Carolina. This method may not suit other centers with more concentrated patient referral areas.

Frequency of contact, according to the current state of the art—if there is one—is best every 1 to 2 months. But frequency really depends on the patient's individual needs.

And our clinic is tailored in that manner.

Most clinics depend on the patients initiating contact. We believe otherwise. We believe that we must maintain contact by our own initiative.

In other words, Senator Stone, we think we are better doctors than the patients are.

How will comprehensive administrative policy satisfy individual need throughout a system of 172 centers? Now, I can't address the issue of reusing pacemakers. I don't think it is an appropriate mechanism for cost containment at this time; that we don't know enough about reusing manmade prostheses that do have a limited longevity.

Senator **Stone**. Thank you, Dr. Rubin.

Of course, the Inspector General's report referred to in your statement was a general report, and your hospital was not in that sample. But we will get to some of the questions that they raise and that you have alluded to as soon as we get through hearing from the rest of the doctors on the panel.

Thank you very much, Dr. Rubin.

Dr. **Innes**. Mr. Chairman, I appreciate the opportunity of helping this committee, I hope, a little bit.

I, too, believe that the veteran deserves a high standard of health care. By my own estimation of the literature and my own surveys, I guess that there probably would be somewhere between 40,000 and 50,000 or 60,000 patients who are veterans who have or who will need pacemakers by 1990. This is a large patient population.

I believe strongly in standards of care in terms of types of pacemakers to be used. I believe strongly in surveillance, and I bring that in the sense that I have started a clinic in Virginia. We have 600 patients in our clinic that saved approximately 3,600 office visits over a year period.

These patients found great security in a telephone surveillance system. We picked up 250 cardia arhythmias, abnormal heart rhythms that had nothing to do with the pacemaker, per se. But these abnormalities of heart rhythm did result in the therapeutic intervention by the referring physician or cardiologist.

We also picked up 30 battery failures in patients who otherwise might not have known that their batteries were failing. Some of those patients were, in fact, asymptomatic; that is, they were without symptoms and had not recognized the fact that the battery was no longer working.

I believe the implant——

Senator **Stone**. Did you pick up those failures by telephone?

Dr. **Innes**. Yes, sir. A rhythm strip coming to an electronic device over the telephone. We were then able to call a referring physician, have the patient admitted, and have the necessary change of battery made.

I believe that we do have some responsibility once the device is in place. And I do think that the surveillance is cost effective.

I think the committee probably recognizes that there are over 100 models and types and manufacturers in this country. The veteran is a transient person. He can go to 172 different hospitals where he can get his health care.

There is some transiency in the medical population in the VA system. Now, the transiency of the patient population makes a centralized data bank of some kind extremely important.

If you recognize the fact that there are, we think, roughly 20,000 patients in the VA system now and the VA does, in fact, pay for the patient to drive to his hospital and allowing for the fact that this patient probably lives at least 10 miles from the hospital, by taking care of those 20,000 patients over the telephone, as far as the pacemaker is concerned, the VA can save over $4 million in gasoline, alone.

If you take that and project it out to 1990, with 50,000 patients, at today's gasoline prices, just by keeping the patient out of the hospital, out of the hospital outpatient department, you can, in fact, perhaps save the VA system some $14 million in travel money.

Just a couple of more brief comments. I believe that this data bank is cost effective. Dr. Rubin and I were talking just before this committee hearing, and he and I both guessed that it cost about $45 each time the veteran comes to the office to have himself checked.

If you can take this outside of the hospital and do it cheaper and do it as effectively, in terms of the surveillance of that pacemaker, I believe, in a cost effective way, you can improve the quality of the health care of the veteran.

Thank you very much for the privilege of speaking.

Senator STONE. Thank you, doctor.

Before I get to the next statement, how, mechanically, does the telephone surveillance work?

Dr. INNES. Well, sir, I am not a giant in that particular industry, but my contemporary to the right is one of the giants in the telephone monitoring industry.

I will answer the question simply. A small electronic device is able to pick up the heartbeat by an electrocardiographic system either on the finger or on the wrist or an electrode placed over the chest.

This is converted into a soundwave and goes over the telephone. A decoder at the other end of the telephone takes the blip, blip, blip and converts it into an electrocardiogram or rhythm strip that tells us something about pace and function, tells us something about the cardiac rhythm.

There are now more advanced computers that can analyze the wave forms and give us much more specific indication or information about the malfunction or the proper functioning of the pacemaker battery.

Senator STONE. Thank you, doctor.

Dr. MORRIS. Mr. Chairman, I have prepared a statement which I have distributed. I would like to, though, specifically confine my remarks now to the general topic of surveillance.

One of the nicest things I had the privilege of doing as a cardiologist is finding a patient who does need a pacemaker. It is a very remarkable treatment device.

With the implantation, though, of that pacemaker, that implanting hospital, that implanting physician, does take on a very, very responsible—additional characteristics, I believe, than regular ordinary patient commitments.

Surveillance I would put into two parts: The direct patient contact or, some artificial contact, telephonic contact.

I believe there are geographic reasons why one area needs more telephone monitoring and others can use more onsite surveillance.

But I don't think that there is any question in our mind, after our pacemaker clinic reviewing the literature, that surveillance by telephone monitoring is a valuable asset to any individual pacemaker patient.

But I want to take it a step further than that. I would concur with the first speaker that perhaps one of the greatest uses for this is whether a pacemaker is malfunctioning or a patient perceives it is malfunctioning, the capability for him to use a telephone system to have his fears allayed is a very important issue.

The idea of surveillance also covers the broader aspect of surveillance of pacemaker performance, not for an individual patient, but how, generically, is a group of pacemakers behaving, how, generically, is a given set of leads working; this figures very much into the problem of recalls and registering.

I think the very effective way to guarantee surveillance of individual patients and surveillance of general pacemaker problems is through the combination of a registry, which is part of the telephone monitoring system. We have found that to be effective on a statewide basis in North Carolina. We have implemented it in hospitals there.

My personal recommendation to the VA would be, they have already adopted a policy of regionalization. I believe that there needs to be some association of VA's in a given region to create their own demands, their own call schedules.

But I would strongly urge for regional centers through the VA system that provide telephonic followup that are the basis for the registry.

I think the individual patient needs and the overall need for accurate recordkeeping can be carried out in an economically feasible and probably much more economically feasible way than any other system.

I will not address myself to the other aspects of this but my advice would be that a registry and a telephonic system be combined as they are natural combination, very cost efficient, and regionalization will allow input from each of the VA centers within all the regions. Thank you.

Senator Stone. Doctor, specifically, what do you mean by regional monitoring?

Dr. Morris. I believe it is impossible to ask 172 VA's to create local registries and local telephonic systems. I am not certain that it is wise to have one national system.

The VA is already divided up into regions, by geographic regions, and I would submit that that might be the most effective way to allow the physician some contact with that regional center.

Senator Stone. How many computers would you use, one for each region or a national one using the regional phone number?

Dr. Morris. Off the top of my head—I am not prepared to answer to details—I would say regionalization for the data bank in the given region.

We had the problem in North Carolina. If you try to create a registry and that registry only exists by legislature, it is hard to get people to comply.

If that data banking is part of the telephonic followup system, it provides a service in addition to capturing the data needed for recall.

So, I would, off the top of my head, say regionalization for record storage allows interaction with the individual hospitals in that region.

Senator STONE. Thank you very much, doctor.

Dr. PARSONNET. Senator Stone, thank you for inviting me here. I would like to preface my remarks by saying that I received queries from Mr. Moore rather late and, because of pressing other responsibilities, my answer was sent to you as a dictated draft. I apologize for spelling and some syntactical errors, and hope that I will have the opportunity to submit corrected copy at a later date.

Senator STONE. Just a minute. I'm not going to let you get away with that. You are the expert, known to be the foremost man in this field.

Dr. PARSONNET. Thank you. I am embarrassed by the text because it was a first dictated draft, and knowing that it was due here on the 21st, I had to rush it along.

Senator STONE. I really thank you for participating, Dr. Parsonnet.

Dr. PARSONNET. I would like to make a few remarks with reference to the questions that were asked in the letter from you.

First, to put some things in context, pacemaker patients are often dependent upon the implanted pacemaker as a life support system. Should a pacemaker fail, suddenly, some 10 to 30 percent of the patients would be subject to a fainting spell, and a few of those patients may be subject to sudden death. But in my estimation, it would be a very small number, not more than 1 or 2 percent.

The purpose of a surveillance system is to detect early change in pacemaker function well before clinical problems become manifest, and also to serve as a laying-on-of-hands, if you will, between the patient and the physician to take care of his general needs.

A pacemaker may become defective or ineffective for a variety of reasons; exhaustion of the battery accounts for approximately 50 percent of pacemaker reoperations today. The remainder of the pacemakers are replaced for electronic failures, factors of wires, problems with the connection to the heart, et cetera.

Even in the modern era of lithium-powered pacemakers, some 20 to 30 percent of patients require reoperation within a 2-year period for problems other than the battery.

Therefore, these two facts—namely, that failure of the pacemaker would be a detriment to the patient's health and that pacemakers fail for reasons other than battery exhaustion—require that a monitor system be developed.

New technology for monitoring exists. Old and still standard methods utilize information derived from special electrocardiograms from which the electrical impulse of the pacemaker was enlarged electronically.

This impulse was studied in regard to its rate and other features, and the pacemaker was also studied for its sensing function, that is, whether it could detect what the heart was doing and respond appropriately.

The simplest surveillance available is at least measurement of the pacemaker rate and evaluation of the electrocardiogram.

New surveillance technology will utilize telemetry for the noninvasive transmission of information from the pacemaker to an external receiving device. This development is in its infancy and cannot be relied upon, as yet, to serve as a surveillance system.

A comment about the advantages of telephone monitoring; monitoring a patient over the telephone involves the use of a piece of equipment which the patient carries with him. This device transmits, at a minimum, the pacemaker rate and a single strip of the electrocardiogram. More detailed information is not ordinarily transmittable, although there is now one private system that is somewhat more complete.

The major disadvantages of telephone monitoring as a sole surveillance system is the lack of patient-physician contact and the inability to inspect the pacemaker wound or to examine the heart or to perform special tests.

Private monitoring services are less effective in evaluating patients and pacemakers. Such services usually evaluate only that information that can be transmitted by the telephone. They do not provide physician interaction, except on a consultative basis, and never provide direct contact between the patient and his own doctor.

It has been shown that pacemaker monitoring is cost effective. The alternative to monitoring is not clinically acceptable, namely, replacement of the pacemaker at a preselected time, because the results of undetected failure may be too serious.

Because no one knows the proper time for elective replacement, by this system, pacemakers are customarily replaced too early and, therefore, the full potential battery life will not be utilized. This will not be cost effective.

Some type of monitoring, therefore, is advisable. For a hospital to maintain a pacemaker clinic and to be cost effective, at least 50 patients should be in the followup program. For those hospitals with fewer than 50 patients, it would be advisable to have patients followed by a coordinated pacemaker center or by a local monitoring service.

I believe that a uniform system for the VA is not acceptable and not feasible because situations throughout the country vary because of geographic differences, and because of differences in patient load.

I would like to make a few comments now about the recycling of pacemakers and reuse. I regard this as a highly advisable project.

The projected battery life of the new lithium pacemakers varies between 5 and 15 years and perhaps longer. Nearly 10 percent of pacemaker patients die within the first paced year, thus making the pacemaker available.

In addition, during that first year about 5 percent of pacemakers are removed for reasons other than death. Cleansing and resterilization of a pacemaker is a simple process and can be done perfectly safely by almost any clinical center.

Let us assume that a lithium pacemaker should be reused if it is less than 1 year old. Knowing that about 100,000 pacemakers are implanted every year, including replacements, and that 15 percent of these units would be available for reimplantation, taking the average cost of a new pacemaker at $3,000, the saving to the public would be about $45 million.

Recycling of pacemakers is now practiced elsewhere. In the United States, it has not been accepted by the manufacturers or by the FDA.

A major problem is the pacemaker warranty which is not transferable from one patient to another. Another problem is retesting of the implanted pacemaker to be sure that it is working properly. And there is also a question regarding the safety because of the possibility of rejection of the pacemaker.

In my estimation, rejection of a pacemaker is exceedingly unlikely and probably will not occur. Experience elsewhere tends to confirm this statement.

I appreciate the opportunity to speak here, Senator. Thank you.

Senator Stone. Thank you.

Dr. Parsonnet, in 1976, the Food and Drug Administration guidelines stated as follows, and I quote:

> The Bureau of Medical Devices and Diagnostic Products has learned of the possible reuse of cardiac pacers. Bureau medical experts have studied this situation and have determined that there is a serious question of whether pacemakers can be properly resterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker. This also poses the problem of foreign protein matter to the second recipient.

Do you disagree with that statement or do you think that things have changed since 1976, with increased use of metal devices, as opposed to plastic devices?

Dr. Parsonnet. I disagree with both. Resterilization is simple. The sterilization gasses will permeate all of the plastic pieces. It will not permeate the hermetically sealed metal part, but neither will bacteria permeate the hermetically sealed metal parts. Therefore, there are no bacteria within the case to cause infections.

So, sterilization of the unit is no problem. The problem of foreign protein I regard as very minor. The amount of protein that would remain on an adequately cleaned pacemaker, either on its metal parts or on its plastic parts, would be exceedingly small.

If one considers the controllable reaction that occurs from a transplantation of an entire living organ, such as a kidney, you can see the difference in magnitude of this problem.

So, I don't believe that there is any medical problem at all. The statement of 1976, I think, is outdated. This judgment can be supported, I believe, by papers and scientific information that is now available from Australia and Europe.

Senator Stone. I would like to ask the other doctors on the panel if they have any comments either about that question or the answer.

And in all the questions that I am going to ask please feel free to respond in addition to the doctor initially answering.

Dr. Morris. I think, technologically, I would absolutely agree. I see no problem with sterilization. I, in fact, believe, probably, devices could be removed and checked. I think, technologically, there is no problem.

But in 1962, 1967, and 1972, I independently sought legal counsel from two different sources at our university, each time bringing up that problem and, each time, sampled a fair number of patients.

I think we are not dealing with a technical problem. I think it is the legal implications: You mean you put a reused pacemaker in my father?

I don't believe that, until the legal barriers are struck down, any company will take back a pacemaker, check it and rewarranty it. There will be no warranty.

So, I think it is a moral and legal question. Technologically, I would have no concern about it. I question whether it is feasible in the United States.

Senator STONE. Because of the lack of a legal warranty?

Dr. MORRIS. Lack of a legal warranty and the way our society behaves in situations like this.

Senator STONE. What did the two independent legal advisers tell you to do about reuse?

Dr. MORRIS. We had a certain number of patients who had great difficulty or no visible support for pacemakers. Even to the point of obtaining informed consent and saying that they were to receive reused pacemakers, our legal advice was you would be completely responsible for that if anything happened to that patient, and the university said that is a responsibility we cannot put our physicians in.

I think that that is the position the VA might place itself in. It would take strong legal advice, rather than technological advice. I think we can tell you it could be done, but the question is should you do it and what are the impediments?

Senator STONE. In recycling a pacer, in addition to cleaning it up, is there not some series of tests and checks that should be made in terms of the electronic levels and the other qualities of standards after it has been used once?

Dr. MORRIS. I believe that that can be done and it could be recertified. I will bow to my colleagues, but I don't think the technological evaluation of an explanted pacemaker is an impediment. I think it could be certified.

Senator STONE. But to your knowledge, the suppliers don't do it?

Dr. MORRIS. I am not aware of anyone in the United States doing that.

Senator STONE. Dr. Parsonnet?

Dr. PARSONNET. No. The manufacturers will not do it because of the problems of warranty. But they can do it. And there was a time before it became a public issue that the manufacturers were willing to do it upon request for a fee of about $300.

There is no problem, whatever, Senator, in testing the integrity of the pacemaker circuit. That is easily done.

Senator STONE. In your view, such testing can be done locally; it doesn't have to go back to the manufacturer?

Dr. PARSONNET. I am sure protocols can be established for doing it by a local service, yes.

Senator STONE. Is it being done now?

Dr. PARSONNET. I guess not openly, Senator.

Senator STONE. Well, that is what this oversight hearing is all about. It is going to be open after today.

Dr. Rubin?

Dr. **Rubin**. Senator Stone, I endorse completely the technical aspects of recycling. But recycling is not exactly like transplantation; you don't have kidneys on a shelf or hearts on a shelf.

But we do have pacemakers on the shelf, and I think that that will be forever the legal impediment that we will face.

We do recycle pacemakers, but not from one individual to another; back to the same individual, which is perfectly permissible. We can cleanup a pacemaker exactly as Dr. Parsonnet suggests we should and can do, and we reimplant the same pacemaker into the same patient when his immediate problem that required explantation is solved.

Senator **Stone**. Dr. Rubin, does the warranty continue?

Dr. **Rubin**. The warranty continues.

Senator **Stone**. So you have not had any legal difficulties with removal, clean up, and reimplantation in the same patient?

Dr. **Rubin**. None whatsoever. And that is permitted by the manufacturers, I believe, in general. And we have received manufacturer advice in that regard.

Senator **Stone**. If you were not going to reimplant but to transplant to another patient, would you notify the new recipient that this was a transplant?

Dr. **Innes**. You would have to tell the patient that. And the others have said—and I would agree with them—that the patients are the ones that would not accept it.

If you suggest to an elderly gentleman that he is going to have a pacemaker put in that was previously used by somebody else, despite the technological advances in testing, the patient may not accept it and may not give you permission to do it and, therefore, you couldn't do it.

Senator **Stone**. You need written permission to do it each time, don't you?

Dr. **Innes**. Yes, sir.

Senator **Stone**. Does the written permission, at least morally, if not legally, have to include the fact that it was used by a first recipient who had passed away?

Dr. **Innes**. Yes, sir.

Senator **Stone**. Is there anything else that you would like to add?

Dr. **Rubin**. Yes. Previously, when we made our first survey, generators were not achieving manufacturers' expected lifetime, and most of these problems were due to difficulties with followup, elective explantation and replacement.

Nowadays, I believe we can, with any given unit in any given patient, more closely achieve manufacturers' expectations of generator longevity through close surveillance.

We are now back to where we were perhaps 15 years ago when we accept an octogenarian or older as a first pacemaker recipient; what is the appropriate choice of a device for that patient? Does he receive a $3,000 programable unit with 15 or 20 or 25 years of battery life, or would it be more appropriate to follow him closely and implant a $1,300 device?

Senator **Stone**. What is the difference?

Dr. **Rubin**. The difference is manifest. Generally, the cost is related to programability and battery longevity. And each——

Senator Stone. Like an airplane engine which you sell according to the number of hours used and the number of hours left; is that it?

Dr. Rubin. Well, I suppose.

Senator Stone. In any event, a $1,300 pacemaker as compared with one costing $3,000 is probably one which was used by someone else; is that correct?

Dr. Rubin. Not correct, no. A $1,300 unit such as might be marketed by Medtronic, Inc., or CPI is one which will have a stated shorter longevity but will have all of the other demand features that a standard pacemaker will have and may suit the patient's needs adequately.

Whereas, a younger person may require a pacemaker for a much longer period. They may require a feature of programing certain parameters to suit a younger, more vigorous individual person's needs, the programability and the longer battery longevity, battery lifetime, would cost more.

So, I believe cost containment can be influenced by appropriate pacemaker choice. And perhaps we will not have to get into the problem of recycling.

Senator Stone. By using smaller or less expensive devices with a shorter life, then, in effect, you would be designing pacemakers for using them to suit the life expectancy of the patient; is that it?

Dr. Rubin. That is correct. And I believe, with appropriate followup, you could put a pacemaker in anybody with a prescribed longevity.

Senator Stone. And, of course, if the longevity is exceeded, you implant another pacer?

Dr. Rubin. That is correct.

Senator Stone. From a consumer safety point of view, is it advisable for a manufacturer to monitor the pacers that it sells to the VA? What should the role of the manufacturer be after the sale to the VA?

Dr. Parsonnet. That is a difficult question to answer. My personal view is that the manufacturer does not and should not have a role in monitoring patients. Monitoring should be a function of a physician or his delegate.

The manufacturers can be extremely helpful in providing devices to follow pacers, but—we physicians, must not turn over the responsibility of followup to a manufacturer. That is not their job, and it is not their expertise.

Senator Stone. If the VA decides to develop more in-house monitoring programs, would it be necessary to make regular use of biomedical engineers in that kind of a followup program?

Is there a role for biomedical engineers in this followup or just the physician or his delegate?

Dr. Morris. I don't think there is any question that these are sophisticated electronic devices which, year by year, are having more and more valuable features and valuable internal checks being designed into them.

It is why I believe this cannot be done on a station-by-station. You cannot create 172 support systems like this. It is not whether it is opt for national or opt for regional. I think that there are pressing reasons to incorporate a very sophisticated data base system for handling the information, analysis, high-level engineering.

So, yes, I think that that is an absolutely necessary part of it. These devices go beyond all but two or three physicians, I think, in the United States in their engineering design.

Senator **Stone**. Finally, in regard to telephonic monitoring, you all seem to favor that. I haven't heard any of you criticize it or downrate it or question its effectiveness.

What kinds of information can you get from using telephonic monitoring? Do some of these systems provide more information than others? What system would you recommend for a large hospital system like the VA?

Dr. **Parsonnet**. I partially answered that in my written statement. The amount of information transmittable by telephone is relatively limited compared to the amount of information that can be obtained by direct examination of the patient and full electronic analysis.

The transmittable information is primarily the pacemaker rate and a rhythm strip of the electrocardiogram, not a complete electrocardiogram.

My statement said that telephonic monitoring is acceptable, but it is not a complete system. It lacks the most important ingredient in patient care, and that is the direct contact between the patient and his physician.

Therefore, in my estimation, telephonic monitoring is in some circumstances satisfactory and an accommodation to patients, but it is not the best system for monitoring.

Therefore, a prescribed system for the entire VA is not appropriate. Some areas would obviously do very well with telephone monitoring where their patients are spread out over a large geographic area.

Other areas, such as a heavily populated, metropolitan area, like the one in which I live, would do very well with an in-house clinical evaluation with full evaluation of the pacemaker combined with telephonic monitoring for those situations in which the patient cannot travel. That is the preferred system. My statement did not say that telephonic monitoring is acceptable for everybody; it is acceptable for some.

Senator **Stone**. I would like to cite Dr. Rubin's published work on the influence of telephonic surveillance on pacemaker patient care.

It appears to indicate not only the need for telephonic monitoring but some detail as to the findings that you made. For example, one of your conclusions that some patients may have died of undetected pacer failures is cited.

Dr. **Rubin**. When we made our first survey, we were unable to account for, it seems like more than half of deaths of pacemaker recipients.

We also noticed that the early death rate was inordinately high among the infrequently followed patients. That is, we were relying on referring physicians in a large geographic area.

We went through our deaths, patient by patient, and some of these patients had died years prior to our inquiry. It was a matter of going through coroner's records, county health records, physicians, family members and to make the closest estimate possible of the cause of death.

Senator **Stone**. Dr. Rubin, do you think that the telephonic system should be used all over the country either exclusively, partially or in conjunction with regular visits or what?

Dr. **Rubin**. We don't pretend to imply that the telephonic system will completely and totally supplant physician contact.

We use our telephonic system to catalyze the contact between ourselves and the patients directly and the patient and his local referring physician.

We have been relatively unsuccessful in detecting by this method pacemaker wound problems. We have taken steps to rectify that and, since our last review, I believe that we are able by telephone to detect, from the patient's words, what problems may exist with a wound and urge the patient to seek either the care of his local physician or to make the trek into the center.

Senator **Stone**. Dr. Rubin, Dr. Innes, Dr. Parsonnet, and Dr. Morris, I want to thank all four of you for your participation today. I think you have clarified a number of these issues which concern the committee. And if we have additional written questions which may come up as a result of the next panel, I wonder if you would allow us to write you and ask for your written responses to those. I want to thank you, again, very much, for participating.

[The prepared statements of Dr. Joseph W. Rubin, Medical College, Augusta, Ga.; Dr. Bruce Innes, University Hospital, Jacksonville, Fla.; and Dr. Victor Parsonnet, Newark Beth Israel Medical Center, N.J.; a letter from Dr. James J. Morris, Jr. to Senator Stone; and the response to written questions submitted by Hon. Alan Cranston, chairman, Senate Committee on Veterans' Affairs follow:]

PREPARED STATEMENT OF JOSEPH W. RUBIN, M.D., SECTION OF THORACIC SURGERY, MEDICAL COLLEGE OF GEORGIA, AUGUSTA, GA.

CONCERNING VETERANS ADMINISTRATION PROGRAMS AND POLICIES RELATING TO THE IMPLANTATION AND MONITORING OF CARDIAC PACEMAKERS

As a representative of the Medical College of Georgia, Section of Thoracic and Cardiac Surgery, I appreciate your invitation and the opportunity to testify before this oversight hearing of the Senate Committee on Veterans Affairs. I will be available to you from 9:30 AM until 12:30 PM on April 23, 1980. We regret that the short notice given to us to prepare testimony will curtail our available time and limit detail in our report.

PREFACE:

In 1974, we inaugurated pacemaker clinics to centralize and improve post-hospital care of patients from Georgia and South Carolina who received cardiac pacemakers at the Medical College of Georgia (Eugene Talmadge Memorial Hospital and the Veterans Administration Medical Center) in Augusta. In October 1976, we added telephone monitoring. By 1979 we had sufficient information to permit evaluation of the influence of telephone surveillance on patient care. We discovered that the frequent patient contact and resulting close familliarity disclosed other life threatening medical problems at a rate that overshadowed the actual technical service of telephone surveillance. As this became known, MCG clinical faculty assigned to the VAMC desired telephone monitoring of VAMC pacemaker patients. VAMC patients were added to the MCG pacemaker surveillance roster for post-hospital care and referred back to the VAMC when any clinical problems became apparent.

RESPONSE TO THE INSPECTOR GENERAL'S INVESTIGATION:

Reaction to the IG investigation of October 1979 regarding procurement and monitoring of pacemakers does not seem directly related to the goals of the

oversight hearing as stated by Senator Stone. With certainty, the immediate result of the investigation was clearly contrary to ideal pacemaker patient care at VAMC, Augusta, as no other appropriate and comprehensive follow-up service was then or is at present available to veteran pacemaker patients. We cannot comment on the IG report of February 13, 1980 because we were not provided with it. The schism forged by IG interference with our patient management may be irreparable at this time.

My personal experience at the hands of the IG was traumatic in as much as the team leveled certain unfounded allegations against me concerning my practice relationship to VAMC, Augusta and post-hospital care of VAMC pacemaker patients. Furthermore, I was required to defend elements of a personal and private conversation with an official of Pacemaker Diagnostic Clinic, Gainesville, Florida, which took place on August 25, 1978, and was reported to the IG out of context. In our opinion, the IG literally waded into our situation at VAMC, Augusta with little knowledge of practice relationships between Medical College of Georgia faculty and the affiliated VAMC. Our programmatic response to the IG investigation was cessation of all post-hospital pacemaker patient care rendered to VAMC patients by the MCG surveillance clinic outside the confines of VAMC, Augusta. We are continuing surveillance of veterans in the registry prior to last October only until other arrangements for follow-up can be arranged through the VAMC.

Since the IG investigation, Pacemaker Diagnostic Clinic and other similar services have repeatedly solicited patient referrals from us. Because we firmly believe that the prescribing and implanting physicians remain directly responsible for long-term follow-up, we cannot justify relinquishing care to primarily technical services removed from the care center. Ethically we can remove ourselves from care only by the direct request of the patient concerned. Referral to an outside technical service only duplicates our obligation to each patient. Despite our stated views and established methods of pacemaker follow-up care at MCG and since the IG investigation, officials from the Veterans Administration have sought to curtail MCG telephone surveillance of our VAMC patients and to limit growth of any existing VAMC surveillance service not subject to prior contract approval. Administrative edict also prohibits the distribution of new telephone transmitters to new VAMC pacemaker patients, a step which we believe to be contrary to enlightened patient care. Although extramural services may be of considerable value and support to the individual practitioner outside a major center such as ours, we ourselves cannot find any direct benefit in subscribing to such an extramural service to the detriment of our own care programs.

MEDICAL UNIT AUTONOMY AND CENTRAL DATA BANKS:

Until the IG investigation, post-hospital care for veterans and non-veterans alike was performed by the MCG Pacemaker Surveillance Clinic. Cost of outpatient surveillance was borne primarily by insurance carriers, Medicare and Medicaid, with patients paying balances according to individual capability. Financial considerations never influenced availability of service to any patient. Because the benefits of close pacemaker follow-up were widely appreciated among MCG physicians, those assigned to provide care at VAMC, Augusta used the surveillance service freely. This is a clear example of our autonomous approach to this patient care area. However, as a sequel to the IG investigation, two parallel services will soon exist. Data from our institutions will no longer be centralized.

Our patient registry is controllable both in size and quality of input, and is immediately available for use by the various specialists involved in each patient's care. The value of a regional or national (centralized) data bank is unknown at present. We seriously question whether a large centralized data bank can improve our patient care. It certainly would duplicate our effort and records which are of immediate importance to and a part of patient management. Larger multi-operator data banks will be only as good as the reliability of input data, and will be of more importance to information specialists than to our physicians. In our considered opinion, responsibility for long-term care resides entirely with the prescribing physicians and this responsiblity includes accurate patient data management.

MONITORING METHODS:

We have knowledge of and experience with two follow-up methods: (1) primary referring physician care with infrequent pacemaker clinic visits, and (2) telephone surveillance. After reviewing our first 12 years of experience with cardiac pacemakers, we discovered that nearly two-thirds of all deaths occurred before replacement of the first generator. In addition, 23% of our patients had died within two years of initial implantation, more than we could account for by advanced age and debility. Furthermore, average pacemaker longevity was considerably less than manufacturers' suggested lifetime. One-third of the study group required an operative procedure more frequently than every two years to correct a suspected pacing malfunction or generator site problem. Our observations led us to suspect that some patients may have died because of undetected pacing failure. We also suspected that some hospitalizations and late complications may have been prevented by more timely patient contact and examinations. Our experience suggested that twice yearly clinic contacts and collaboration with referring physicians were not uniformly achieving treatment goals.[1]

In response to our initial study, telephone surveillance was established along with a continuously updated registry of patients who received pacemakers on any clinical service of MCG, either at Eugene Talmadge Memorial Hospital or the VAMC, Augusta. Telephone surveillance increased patient contact while decreasing patient attendance at clinics and hospitalizations for investigation of suspected malfunctions. Pacemaker longevity was increased to more closely approximate manufacturers' projections except in the cases of generator malfunction and unit recalls. The knowledgeable surveillance nurse specialist who serves the prescribing and implanting physicians was able to detect not only occurrences of pacemaker malfunction but also other life threatening problems often unknown to the patient or the family physician. In most instances a telephone call to the referring physician initiated timely care and on occasion the patient was summoned back to MCG for further attention. Our recent review of the telephone surveillance experience clearly demonstrates a decrease in post-implantation mortality rate and a decrease in reoperation rates for premature replacement and suspected lead problems.[2]

COST EFFECTIVENESS OF PACEMAKER SELECTION AND PROCUREMENT:

Cost is not a primary consideration for pacemaker choice. Unit reliability, manufacturer integrity, service, and experience, and physical characteristics of leads and generators remain the major reasons for choosing one unit over another. A need for pacemaker programmability and battery longevity are major influences upon initial cost. The appropriate choice of pacemaker unit for any given patient can only assure cost effectiveness.

WHY SURVEILLANCE?

Once the scars of implantation are healed, the patient's problems remain. A pacemaker does not remove the disease for which the pacemaker was implanted. The pacemaker is intended to maintain cardiac action and blood flow during periods of faulty cardiac rhythm. Some patients are continuously dependent upon the pacemaker's function, others are intermittently dependent. The patient is at a constant predictable risk of failure of some part of the pacing system, progression or development of heart disease, or abnormal rhythms which can interfere with the anticipated performance of the pacing system. Battery exhaustion will probably account for a decreasing incidence of pacemaker failure. Our published experience has demonstrated longterm benefits of telephone surveillance by early detection of malfunction, maximizing generator longevity, decreasing hospitalisation, and increasing patient security.

Postoperative management includes electrocardiographic evidence of generator and lead function, as well as overall assessment of the patient's condition. New technologies may make analysis of pacing characteristics more accessible. However, knowladge of changing electrode resistivity and sensitivity are now most commonly available only by operative access to the pacemaker implantation site. We do not expect requirement for frequent follow-up to be diminished by newer technologies because of the constant evolution of electrophysiological and pathological phenomena at the electrode to heart interface.

ADVANTAGES OF TELEPHONE MONITORING:

Telephone monitoring provides a diagnostic electrocardiogram, heart and pacemaker rates, and pulse width. With this information, unit longevity may be projected, and system function assured. In addition, the integral pacemaker clinic and surveillance service can follow the patient's other conditions at any frequency necessary. Furthermore, the individual patient can participate in follow-up wherever a telephone may be without disrupting day-to-day life and this method of intermittent observation may be equivalent to frequent personal contact between the patient and his physician. The technical detection of generator end-of-life and pacemaker malfunction are but a part of comprehensive patient monitoring.

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2. Rubin JW, Ellison RG, Moore HV, Pai GP, Frank MJ, Killam HAW: Influence of Telephone Surveillance on Pacemaker Patient Care. J Thorac Cardiovasc Surg 79:218, February 1980.

This concludes the testimony of Joseph W. Rubin, M.D. before the oversight hearing of the Committee on Veterans Affairs, Washington, DC, April 18, 1980.

RESPONSE OF DR. JOSEPH RUBIN TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN CRANSTON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. Without mandating a specific schedule for attending physicians at VA medical centers, what balance of clinical and telephonic monitoring of pacemaker patients do you believe would be a realistic guide for a minimum surveillance program in the VA health-care system?

Answer 1. Schedule: The balance between clinical and telephonic monitoring depends entirely on the type of practice. When patients reside in a small area like a major urban center clinical contact may be superior to telephone monitoring. On the other hand, in a practice such as ours with patients spread widely in a 300 mile radius, clinical visits are far less practical than telephone monitoring. Because complications of pacing occur most often within the first six months following first implantation, contact may be as frequent as weekly during this initial period. Subsequently patient contact may be spaced at one to two month intervals. Monthly intervals are probably ideal. Closer attention must be paid to patients who are absolutely pacemaker dependent whereas other patients who have an insidious onset of symptoms after pacing failure may be picked up during the monthly contact. Longer intervals increase the proportion of patients having recurrence of symptoms after pacing failure. A pacemaker dependent patient who demonstrates one adverse event on electrocardiographic monitoring may be telephoned more often than weekly until the problem is solved. A realistic guide for minimum surveillance of a chronic implant is a frequency of six to twelve times per year.

Question 2. On what do you base your belief, which you stated during your oral statement during the April 23 hearing, that the VA might attempt to implement uniform regulations for pacemaker followup?

Answer 2. Uniform regulations: In my previous testimony I drew a distinction between policy and regulation. I believe that the VA may establish general guidelines or pacemaker surveillance but regulation will certainly not be applicable for every pacemaker practice within the VA system. In other words, we believe that centers should have the freedom to operate within guidelines established by the requirements of regional practice.

Question 3. Please provide the Committee with a copy of the information from pacemaker manufacturers that you received with respect to the reimplantation of pacemakers in the same patient to which you referred during the April 23 hearing.

Answer 3. Reimplantation of pacemakers in the same patient: Whenever we have removed a functioning pacemaker from an individual because of a complication not related to the generator we have invariably sought the verbal instructions of the manufacturer regarding cleansing, repackaging and sterilization. Medtronic, Inc. provides resterilizing instructions for reuse in the same patient with original package inserts. Where possible reprocessing is performed within the hospital. Because of the time involved and the need to reimplant the unit at some early date we have not found it practical to return the unit to the manufacturer for reprocessing for the same patient. Whenever a unit is packaged in the hospital an attempt is made to follow the manufacturer's instructions precisely.

Question 4. Please describe the pacemaker surveillance program that was in place at the Medical College of Georgia prior to the Inspector General's September 1979 investigation at the Augusta, Georgia, VA medical Center.

Answer 4. Surveillance program: The Medical College of Georgia Pacemaker Clinic was expanded in October 1976 to include telephone monitoring. Outpatients from Medical College of Georgia hospitals (including VAMC) were offered surveillance to increase the frequency of patient contact regardless of financial considerations. However, an attempt was made to bill patients who were able to pay for services through third party payers.

Question 4A. What services were provided?

Answer 4A. Services are provided through contact by a pacemaker clinical nurse specialist. Each contact is individualized according to patient needs and includes interrogation for cardiac and neurological symptoms, wound problems and an electrocardiogram. The nurse also visits pacemaker patients whenever they are hospitalized for any reason.

Question 4B. On what do you base your belief that the Inspector General's investigation had a detrimental impact on that surveillance program?

Answer 4B. Inspector General's investigation: When the Inspector General's team made their allegations against me I ceased my participation in surveillance services to veterans in the Medical College of Georgia Pacemaker Surveillance Clinic outside the confines of VAMC. Despite general acceptance of the Medical College service by consulting VA physicians, VA residents, and interns, no further services were offered to VA patients after the investigation. The Pacemaker Surveillance Clinic continued to carry veterans already in the program until alternative arrangements could be made for their surveillance. That was the impact of the Inspector General's investigation.

Question 4C. Please describe any detrimental impact you believe that that investigation has had on the care of veterans with pacemakers who are patients at the Augusta VA Medical Center.

Answer 4C. Detrimental impact: Despite having the easily accessible Medical College of Georgia Pacemaker Surveillance Clinic at the disposal of VA physicians, the Cardiology Service in VAMC found it necessary to duplicate our already established clinic with as yet uncertain results. The same physicians serve both clinics. Because of the allegations brought against us by the Inspector General we saw no reason to expose Medical College of Georgia Pacemaker Clinic personnel to further investigation and incursions by external agencies such as the Pacemaker Diagnostic Clinic of American.

Prepared Statement for the Senate Committee on Veterans Affairs by Bruce J. M. Innes, MDCM, FACS, FACCP, FRS, Professor of Surgery, University of Florida, Chief, Division of Thoracic and Cardiovascular Surgery, University Hospital of Jacksonville

Mr. Chairman and Members of the Committee,

It is a privilege to have an opportunity to testify for the Senate Committee on Veterans Affairs with respect to pacemakers.

It is my own personal belief that the veteran has an inalienable right to quality medical care. There may be in excess of 20,000 veterans in the United States who currently have pacemakers implanted at this time. Pacemakers are currently implanted in over 100 Veterans Administration Hospitals and some of these institutions do monitor some of these patients some of the time. It is my feeling that the veterans who have served their country deserve the best quality medical care that can be made available to them and it is clear from available reports from a variety of sources and from personal communications within the V.A. system that the standard of care for these pacemaker patients is highly variable. We should recognize that the veteran is, in fact, part of a captured population in the sense that these patients receive most of their medical care from 172 Veterans Administration Hospitals throughout the country. It would seem reasonable that we should, in certain subsets of diseases and medical procedures, try and achieve some form of standardization. Standardization will provide the veteran with the kind of care he deserves and will give the medical community a series of statistics and analyses and standards that will give us a long term view of the patient with a pacemaker in place.

We should recognize that the veteran, as a patient, is part of a transient population since many veterans move from city to city and must have their medical records transferred in a like fashion. This transiency can confuse the issue when the practice of medicine is involved as it relates to the pacemaker science. Standards of pacemaker care and indications for pacemaker care are so variable in different regions of the country. We should recognize that the V.A. physician population is likewise transient. Statistics have shown and analyses of medical staffing problems have indicated that on occasion several different chiefs are appointed to a given medical division in a given hospital in a given calendar year. If a physician in the V.A. system is in charge of a pacemaker patient and the physician then leaves and a new chief brought in, then the new chief has the prerogative of changing guidelines, principles, indications, standards of care, etc. to suit his medical principles, such that the continuity of care for a given veteran is almost impossible. It should be recognised that there are over 100 models and manufacturers of pacemakers; and therefore, a continuum of care in a standard manner is, again, impossible.

It has been shown under certain circumstances that a given model of a pacemaker costs $1,000 more or less in different parts of the country. This, to me, is an inconceivable waste of taxpayers money. It is my belief that there should be a central data bank where all pacemaker patients can be monitored and statistics kept. Whether the actual monitoring of the patient electronically is done at the local individual hospital, regional or national level is up to the Veterans Administration to decide. My own experience with establishing a 600 patient clinic on the east coast of Virginia has shown that over the years we have managed to pick up in excess of 250 different instances of cardiac rhythm abnormalities that have required therapeutic intervention. The telephone monitoring, per se, was specifically designed for monitoring pacemaker patients for the pacemaker system itself, but in monitoring these patients we found that a large number developed cardiac rhythm abnormalities. In the six years of the clinic experience we picked up over thirty premature battery failures, and it is for these two reasons that surveillance of pacemaker patients is obvious. Pacemaker patients need to have surveillance and follow-up of their pacemaker system simply because it is an electronic device and while it may carry a warranty of a certain length of time, there is no guarantee that the electronic components and lead systems will not fail during their normal life span in the pacemaker. How this follow-up is done and how the surveillance is carried out is a matter of philosophy, but there is an absolute need for monitoring these patients. I believe that there are statistics available within the V.A. system that show that a large number of patients are not being followed at all. Some patients have not been followed until the warranty on their pacemaker has expired and I believe it can be shown that certain patients have actually died because of pacemaker failure and because of the lack of surveillance. Despite the technology in this country and despite the technology of pacemakers as they now exist, there are limitations to pacing devices. The widespread use of nuclear pacemakers is not practical because of the regulations of the Atomic Energy Commission. Therefore, the long term lithium batteries which are now commonplace in the pacemaker world do have some limitation in terms of time that they can be implanted but this time is, as yet, undetermined. The length of time that a battery can stay in place is directly proportional to the amount of time the device is actually used by the patient. The committee should recognize the fact that in some patients the battery is implanted and, in fact, the patient's heart does not utilize it 100% of the time. These are called demand pacemakers, and, as such, when the heart rate fails below a given set point, then the pacemaker system takes over until the patient's own heart rate picks back up above the signal level as set. There is no question that the indications for pacemaker implantation have changed in the last four or five years and there are now several disease processes or cardiac physiologic problems that now warrant pacemakers that didn't warrant such a device several years ago. We are now beginning to see the World War II veteran reach that age group where pacemaker implantation is going to become more commonplace. I think the perspective and indications for such devices are going to increase as time goes on and with an increasing number of pacer patients in our population it makes proper surveillance even more important. I was distressed to learn that, in fact, in some institutions pacemaker patients are not followed by telephone, but are recalled by the institution for their follow-up care. If a patient has to drive 200+ miles for which he gets paid 10¢ a mile to have his pacemaker checked, surely this is more expensive than a $25 phone call. In the experience with pacemaker telephone clinics we have shown that we can decrease the number of actual office visits within the pacemakers systems and, therefore, we can, in fact, save the patient energy and driving time and the utilization of gasoline by monitoring his pacemaker over the phone.

I would point out to you that a wide variance occurs in the price of pacemakers with a wide variety of models to choose from. It has come to our attention that some very expensive, long life pacemakers have been implanted in patients whom we could predict statistically would not outlive the life of the pacemaker. For example, if you have an 85 year old man who gets a ten year pacemaker costing somewhere around $7,000 for the device and hospitalization when he will only be using that pacemaker less than five years, this seems an unreasonable cost for the care of that patient. Understanding actuarial tables and understanding the physiologic age of the patient, an 85 year old gentleman could probably have a three or four year pacemaker put in at considerably less cost and should he outlive that pacemaker another short life pacemaker could be implanted and the ultimate cost will still be less than the ten year or twelve year pacemaker that might have been put in originally.

I would like to make several other comments since you queried the advisability of recycling pacemakers. I would tell you that this is not common medical practice as it relates to infection, the individual's body chemistry and the reaction on the pacemaker container, and as it relates to the inability to properly cleanse and sterilise a pacemaker that has been previously used, and the lack of knowledge as it relates to the effect of sterilisation on the pacemaker systems, per se, and in terms of its effects on the electrical system therein. The reasons for monitoring a patient in a standard way is to pick up premature battery failure, lead dislodgment, and problems with the pacemaker system itself. It is necessary to recognise cardiac rhythm abnormalities and for the analysis of the battery function once it has been implanted. The advantages of such a system are that it will pick up cardiac abnormalities, battery and lead malfunctions, and computerisation of studies are now available for wave form analysis which allow us to electronically analyse the actual function of the pacemaker systems and leads. Another major advantage of a monitoring system is for long distance purposes, per se, as it does decrease the number of office visits that are necessary within the V.A. system. If a pacemaker is implanted, and a veteran needs to be followed in the immediate post-operative period to be sure that there is no infection and for a clinical evaluation of his pacemaker status, once the wound is healed one can save [illegible]where between 20 and 30 thousand outpatients visits a year in this [illegible]cemaker population. The saving of 20 to 30 thousand office visits will also save energy in terms of the travel that a patient must undertake to reach a regional center. A standard monitoring system as suggested will allow for transiency of the patient population, standardization of care, and take into account the multivariance factors that are created by a transient medical physician population as outlined above.

I would like to make the following recommendations which should be prefaced by a comment that I do not think that the practice of medicine should be mandated by the government to any individual physician. The fact of the matter is that these patients are essentially being cared for through the Veterans Administration which is a governmental organization. The Veterans Administration has seen fit, in many ways, to control its medical practices in other areas, but I do think that we should give the individual practicing Veterans Administration cardiologist and cardiac surgeon certain latitude in the way he cares for his patients, but that we should have some restrictions and some standards of care by which we could abide. There should be an active committee established by the V.A. of cardiologists and cardiac surgeons as well as extramural pacemaker experts. This committee should sit down in an honest and frank way, pick out three or four models and types of pacemakers that will meet the needs of our population, that will give the implanting surgeon some choice in the device which he uses and once we have picked out the appropriate models and manufacturers we should then go to these individual manufacturers and put the pacemaker purchases out to bid. If the Veterans Administration is going to buy somewhere between three and eight thousand pacemaker systems a year, then the price from the individual manufacturers should certainly be on a competitive basis. If the V.A. could guarantee a manufacturer a certain portion of the business, then that business should see to it that it's worthwhile for his own company as well as being less expensive for the V.A. in general. Once we have established the models and types of pacemakers to be used then the committee should establish the standards of surveillance that shall be carried out. It would seem to me that the Veterans Administration and its bureaucracy and the chiefs of medical services divisions of the V.A. should be able to make certain policies to the individual V.A. Hospitals. I recognize from personal communications within the V.A. system that individual physicians, at times, will not comply with some of the V.A. mandates. If such a committee was established and met honestly and provided us with the best possible recommendations that are available in this country, then it would seem that the standard of care we are looking for could be achieved. I would personally recommend that a centralized data bank on pacemaker surveillance should be established, but certain criteria should be recognized for the frequency of surveillance, the frequency of wave form analysis, and telephone monitoring. It has been shown that there are some patients who actually remain asymptomatic and actually have a failing pacemaker in place. The asymptomatic patient is, in fact, at far more risk than the patient who develops symptoms as his pacemaker fails. I think the committee could establish an appropriate cost analysis of follow-up and I believe it can be shown that telephone surveillance, in the long run, will be less expensive as it will reduce the number of pacemaker batteries that must be changed and can, in some measure, prolong the pacer life. For example, if you have a pacemaker that is supposed to last five years and at the end of that five years the pacemaker is still functioning, as well it might, since the patient may not use it all of the time even though it is actually in place, then we can extend the life of that pacemaker until there is electronic and telephone evidence that the pacemaker is beginning to fail. In our own experience, some years ago, before telephone surveillance was established, pacemaker batteries were routinely changed at two years. Obviously the technology has improved and the length of battery life has increased, therefore, routine changing of batteries is no longer necessary. With a standard surveillance system we can extend pacer life beyond its warranty period and in some instances up to two or three years. For every year that one does not have to change a battery as a routine, one is saving the system somewhere between three and five thousand dollars for the cost of the battery and/or hospitalization. In this era of cost containment and the need to reduce the amount of money spent on health care it seems only appropriate that standards of care and surveillance of pacemakers will, together, achieve a tremendous savings for the Veterans Administration.

Respectfully submitted,

Bruce J. M. Innes, M.D.

(Insert 4)

DUKE UNIVERSITY MEDICAL CENTER

Department of Medicine
Division of
Cardiovascular Disease

April 22, 1980

Richard Stone
United States Senate
Committee on Veteran's Affairs
410 Russel Senate Office Bldg.
Washington, D. C. 20510

Dear Senator Stone:

I am writing in response to your letter of April 9th, regarding a committee hearing on Veteran's Administration programs, on policies relating to implantation and monitoring of cardiac pacemakers.

In your letter you referred certain specific statements and wished my views on those facts. I shall restate the questions and briefly express my views.

1) Why is surveillance of pacemaker recipients necessary? a) The entire pacing system is subject to failure and therefore surveillance is manditory. b) Malfunction of the pacing system maybe preciptous and complete, on the other hand it may be very transient and intermittent. All gradations exist in between and many of these can only be detected by surveillance. c) Several modes of failure of the pacing system are inapparent to the patient. d) Certain design characteristics are engineered into the pacing devices that allow one to predict the end of the pacemakers life or impending failure and surveillance is the only way to detect this. e) Pacemaker failure, once it has occurred, may not immediately produce symptoms but if left uncorrected may at a later date produce a catastrophic result and therefore surveillance can avoid dangerous and costly medical emergencies.

What are the limitations of pacing devices from either a technical or medical viewpoint? Pacing systems consist of basically three parts; a) pulse generator b) lead system, c) the patient's own heart and bodily reactions. The pulse generator or pacemakers are currently rather effective devices with low rates of random failure in the first several years (4 to 6 years), but random failures do predictably occur, and they need to be detected. Pacemaker leads - malposition, fracture, partial breaks constitute a rather predictable and steadily accummulation of failure modes over time. Currently, leads probably represent a more likely threat to pacemaker malfunction in the first several years than the generator itself. Finally, biologic problems. Inherent in the patients own reactions ie; threshold elevations, failure to sense, errosion, infection all tend to accummulate over time. When one takes all three general reasons for pacemaker system malfunction ie; pulse generator, leads, and patient related failures, although each is rather low, the combined total pacemaker system failure is unfortunately rather high and generally random in its occurrence and can only be reliably and predictably detected

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by a system of repeated observations and surveillance.

Discuss the perspective for these devices in terms of the impact of new technologies on surveillance requirements. Pacemakers are being marketed which have potentially greater biologic value ie; dual chamber pacing, atrail synchronous pacemakers, pacing for primary rhythm disturbances, etc. All of these advantages will increase (amount?) the potential for a malfunction and will tend to increase the demands for surveillance, if these biological advantages are to be utilized. Overall technological advances have improved pacemaker systems, but the current rate of overall system failure appears to be high enough to warrant surveillance and in my opinion the complexity of the new systems will not decrease but only increase the need for surveillance and provide greater opportunities through surveillance to detect impending failures.

2) What are the advantages and disadvantages of telephonic cardiac pacer monitoring? If one assumes that surveillance of the pacing patient is required, two basic methods are available; a) remote (telephonic), b) on-site, direct patient contact (clinic, nurse, physician). Atleast three major considerations impact on this choice. a) Geographic - patients located in highly concentrated urban areas may in fact be within short and relatively easily accessible distances to an on site visit. Conversely patients in a rural or semi-rural area, may be several hundred miles from implanting centers. b) Medical conditions - certain patients may have as their only dominant and medically important problem, the condition which resulted in their pacemaker implantation. Their surveillance will be minimal and will depend on the specific pacemaker system. Conversely, a patient with multiple and complex associated and unassociated problems, may be under such close medical attention, that surveillance is in fact, covered by their frequent medical contacts. c) Emergency situations - the sudden appearance of real, or precieved patient related pacemaker problems is a frightening and important situation to a pacemaker patient or his family. The capability for telephonic monitoring provides a very rapid and important instantaneous solution to a large porportion of these problems and avoids frequent and unscheduled emergency visits.

3) Evaluate the scope of information transmitted and the services offered by private monitoring services, including a central patient and pacemaker register. The large number of devices, models, various normal operating conditions produce a rather wide body of knowledge that a practicing physician must be required to learn for multiple different pacemakers. This is not a uniformly understood bit of knowledge that is in the hands of all physicians. In fact, the presence of a pacemaker system may interfere with the care of a patient by a physician who lacks this knowledge. I have had several hundred patients on telephone monitoring systems through two commercial firms and our own hospital base system. I consider electronic monitoring with an adequate system for recording the pacing spike and the electrocardiogram a totally acceptable system. Accurate RR pacer spike intervals and an electrocardiogram showing appropriate capture are in my opinion currently all that is required for adequate monitoring. Pulse duration and wave form analysis have not in my opinion added enough extra information to justify their routine use.

Perhaps the most important function of a follow-up telephonic system is that intrensicly and inherently it is in fact a registry with up to date information on each patient. A well run firm provides for accurate, consistent follow-up with reliable registry functions. When this is carried out at individual sites they will of necessity be unequal in the various locations and frequently fail in both the surveillance and the registry components. In summary surveillance is a necessary part of the care of the pacemaker patient. In certain settings urban, in a patient with multiple associated problems, onsite visits may be most appropriate and the major reason for a telephone system is its registry function. In others, telephone follow-up may be far more economical and feasible because of distances, etc., and can be the major form of surveillance. In my opinion all patients should have the capability for telephone follow-up. Some for frequent surveillance, others for infrequent surveillance, but all for emergency and creating a permanent up-dated registry. The frequency of their telephone calls can be tailored by geographic, associated medical conditions and the sophistication of the medical community in which they live.

4) What are you opinions on a cost effective method of cardiac pacer monitoring for a system of 172 V.A. Hospitals? For adequate patient care, for effective registry information, I believe the V.A.H. should have central pacemaker follow-up centers with the primary function of surveillance and up-dated registry information. In view of the regionalization already underway in the V.A. Hospital system, it would appear wisest to have regional, dedicated pacemaker follow-up areas. The frequency of contacts, the ratio of telephone to on site visits be determined independently by the implanting physician, but all patients should be placed on a minimum number of yearly calls ie; every third or fourth month to provide a usable emergency system and to continously up-date the registry. In terms of cost effectiveness, regionalization would be most important because it is clear that well trained technicians, suitable data banking conditions and manning a 24 hour emergency call system is not the problems of an individual V.A. Hospital.

Discuss the advisability of recycling pacemakers. What is the extent of the reuse practice in foreign countries? What are the technical and medical problems of recycling? Would recycling create public relations difficulties? I have on multiple occasions discussed the question of recycling with patients and have sought legal opinion. My own belief is that our society would not accept the idea of a recycled pacemaker and would allow the V.A. Hospital to place itself in potentially serious legal situations. I have no further knowledge on this problem.

In the second paragraph of your letter of April 9th you discussed the Inspector Generals report of February 13, 1980. In reviewing that document I think it is very clear that the necessary steps regarding selection and procurement of pacemakers very clearly needs to be re-evaluated in a strict business sense in addition to many problems regarding storage, etc., straight out rigid administrative control over procurement and storage appear indicated.

My final over-view would be that the implantation of a pacing system in a patient is a very gratifing medical experience when it is appropriately carried out. With that implantation, however, the implanting hospital and physicians assume a very important direct responsibility to that patient. 1) They may delegate a portion of the follow-up to a private physician or to a repeatedly changing V.A. staff, but the overall consideration is that the hospital, implanting surgeon and that V.A. system acquire a serious long range obligation for surveillance of that device. It would appear to clearly be the responsibility of that implanting center to maintain accurate records regarding the specific pacemaker and its components implanted; to carry out continued surveillance to detect impending failures, to warn that patient if there is unsatisfactory performance in that specific model and to appropriately act when pacemakers of a similar type are reaching the end of their effective performance. I do not know any way short of a telephonic and registry system which can carry out this process uniformly over a wide system. The opposite view, that no surveillance is necessary or that it can be left in the hands of individual V.A. Hospitals, leaves the entire V.A. system open to serious moral and medical long range threats.

Thank you for your attention to this matter.

Sincerely yours,

James J. Morris, Jr., M. D.
Professor of Medicine
Department of Medicine
Division of Cardiology

JJM/lr

PREPARED STATEMENT OF DR. VICTOR PARSONNET, DIRECTOR OF SURGERY, NEWARK BETH ISRAEL MEDICAL CENTER, NEWARK, N.J.

1. NECESSITY FOR PACEMAKER SURVEILLANCE

Pacemaker patients are often "depenoent" upon the implanted pacemaker as a life support device. Should a pacemaker fail suddenly, some patients (10–30%) are subject to sudden fainting spells; some of these are subject to sudden death (but not more than 1% or 2% of the total). The remainder would suffer a return to the status quo ante, which was, of course, an unsatisfactory but not necessarily a life threatening medical condition. Some time thereafter, the original condition would make itself manifest, and the patient would experience a recurrence of those symptoms that required the pacemaker implantation. The purpose of a surveillance system is to detect early change in pacemaker function before failure occurs, and well before clinical porblems would become manifest.

Pacemaker may become ineffective for a variety of reasons. Exhaustion of the battery, the most common reason in the past, account for approximately 60% of pacemaker reoperations. The remainder of the pacemakers are replaced for a variety of other reasons, such as electronic failures, fractures of wires, and problems with the electrode connections to the heart. Even in this modern era of lithium-powered pacemakers, some 20–30% of patients require reoperation within a three year period for problems *other than* battery exhaustion. Therefore, these two facts, namely that failure of a pacemaker would be detrimental to a patient's health, and that pacemakers fail for reasons other than battery exhaustion, often in unusual ways and at unexpected times, require that a monitoring system be developed.

New technologies for surveillance do exist. Old methods utilized information derived from special electrocardiograms from which the electrical impulse of the pacemaker could be enlarged electronically. This impulse was studied with regard to its rate, wave shape, amplitude and duration, as well as the relationship between the output of the pacemaker and the cardiac response. One also evaluated the sensing function of the pacemaker to assure that it would respond adequately to cardiac activity (so called "demand" type pacemaker). Simplest surveillance included at least measurement of the pacemaker rate and evaluation of the electrocardiogram.

New pacemaker surveillance technology will include telemetry, or non-invasive transmission of information from the pacemaker to an external receiving device. This development is in its infancy, and cannot be relied upon as yet to serve as a surveillance system.

2. ADVANTAGES AND DISADVANTAGES OF TELEPHONIC CARDIAC PACEMAKER MONITORING

Monitoring a pacemaker patient over the telephone involves the use of a piece of equipment which the patient carries with him. This device transmits at a minimum the pacemaker rate and a single strip of the electrocardiogram. The other information, such as wave shape, amplitude and duration is not ordinarily transmitable.

The major disadvantage of telephone monitoring as a sole surveillance system is the lack of patient-physician contact, the inability to inspect the pacemaker wound or to examine the heart, or to perform what is called "external overdrive", a technique by which the pacemaker function can be supressed temporarily. External overdrive permits evaluation of the basic underlying electrocardiographic rhythm, and provides an evaluation of the sensing circuit of the pacemaker. The advantages of direct patient-physician contact require no elaboration.

Private monitoring services are effective in evaluating pacemakers and patients. Such services usually evaluate only that information that can be transmitted by phone, which, with few exceptions, include only the pacemaker rate and a single strip of the electrocardiogram. At least one company (PCA) can now transmit more electronic information than in the past, but the effectiveness of their system has not been documented. In any event, private services do not provide physician interaction except on a consultative basis, and never provide direct contact between the patient and his own doctor.

There are a number of pacemaker centers throughout the country in which all the full services mentioned above are provided. These tests include complete electronic monitoring of the pacemaker, phone monitoring between personal surveillance visits, and periodic interrogation, examination, and consultation with the patient by a physician. Registries are maintained in order to compare the status of the pacemaker to its previous condition, and in order to maintain a tight follow-up surveillance system.

3. COST EFFECTIVENESS OF CARDIAC PACEMAKER SURVEILLANCE

It has been shown by us and others that pacemaker monitoring is cost effective. The alternative to monitoring is not clinically acceptable, namely replacement of the pacemaker at a pre-selected date because results of undetected failures are too serious. Because no one knows the proper date for elective replacement, by this system pacemakers are customarily replaced too early, thus all of their potential battery life has not been utilized. Even nuclear pacemakers, initially more expensive pacers, when monitored at regular intervals are cost effective.

Thus, some type of monitoring system is advisable, not only for patients in non-Federal institutions, but for the VA hospitals as well. For a hospital to maintain a pacemaker clinic, at least 50 patients should be in the follow-up program. For fewer patients the expense of maintaining the equipment and personnel for the monitoring system are too great. Therefore, a full pacemaker clinic should best be confined to a hospital where there is a large patient load.

For those hospitals with fewer than 50 patients, it would be advisable to have the patients followed by a coordinated Pacemaker Center, or by a local monitoring service, or by a telephone monitoring system which could be set up by each VA hospital. Even though the telephone monitoring system is not as effective in detection of impending pacemaker failure as is a full pacemaker clinic, it will still detect most problems in advance, especially if the process is combined with a periodic visit to a regular cardiac clinic for examination and interview by a physician.

4. RECYCLING OF PACEMAKERS

Recycling pacemakers is a highly advisable project. The projected battery life of the new lithium pacemakers varies between 5 and 15 years. Ten percent of patients die within the first paced year, thus making the pacemaker "available." In addition, in that time about 5 percent of pacemakers are removed for reasons other than death. These, too, would be available for reuse. Cleansing and resterilization of a pacemaker is a simple process and can be done by almost any clinical center.

Let us assume that a lithium (or nuclear) pacer should be reused if it is less than 1 year old. Knowing that about 100,000 pacemakers are inserted a year, one may then anticipate that 15 percent of these units would be available for reimplantation. (The figure of 100,000 is the sum of new and replacement units implanted in 1978 as determined from a survey conducted in 1979.) Considering an average cost of a new pacemaker to be $3,000, the savings to the public would be approximately $45 million a year. (The cost of refurbishing the pacemakers, even if borne by the manufacturer, would be no more than $300 per pacemaker, or $1 million.)

Recycling of pacemakers is now practiced extensively in Europe, and has become a policy in some areas. But in the United States recycling has not been accepted by manufacturers or the public. The FDA, although not formally approving or rejecting recycling, has not come out in favor of this policy. A major problem is the pacemaker warranty, which is not transferrable from one patient to another. Another problem is the retesting of the explanted pacemaker. There has been a question regarding the safety of recycling because of the possibility of foreign protein material that might produce a "rejection" of the new unit. This is an overblown problem, because the modern pacemaker is entirely encased in an hermetically sealed metal can, its Silastic rubber pieces can be cleansed thoroughly with techniques that have been well described, (Mond, et al.); and in my estimation, rejection of a pacemaker would be exceedingly unlikely. Experience elsewhere tends to confirm this statement.

Response of Dr. Victor Parsonnet to Written Questions Submitted by Hon. Alan Cranston, Chairman of the Senate Committee on Veterans' Affairs

Question 1. Without mandating a specific schedule for attending physicians at VA medical centers, what balance of clinical and telephonic monitoring of pacemaker patients do you believe would be a realistic guide for minimum surveillance program in the VA health-care system?

Answer 1. You have asked about a satisfactory balance (proportion?) between clincial and telephonic monitoring. I assume that clinical implies the following ingredients: Interview and examination by a physician; analysis of the pacemaker output; electrocardiogram; and other tests that should prove necessary. I assume that by telephonic monitoring is meant, at a minimum, transmission of pacemaker rate (interval) and an electrocardiographic rhythm strip. This question is a bit difficult to answer, because it is my impression that patients in the VA often do not have private physicians who, in the private sector, would ordinarily do some of these examinations. With that in mind, I would suggest the following:

(a) Patients should be seen by a physician for the mentioned test at least three times a year.

(b) Telephonic monitoring should be done according to the presently approved Medicare schedule.

Thus the telephone monitoring clinical evaluation ratio would be about 1:3.

Question 2. In your opinion, if a minimum of telephonic monitoring is adopted by the VA, should the VA set up an in-house system to provide that service to its pacemaker patients or contract with a private monitoring entity?

Answer 2. You have asked if "telephonic monitoring is adopted by the VA"—etc. The question itself has an implicit faulty concept. No single system of followup will satisfy *every* VA pacemaker center. Such a concept is to be feared, because of the obvious dangers of mandated uniformity in any system. Good patient care will not result from a uniform system throughout the entire VA. I would, however, endorse the following:

(a) The VA should insist upon a uniform registry so that all patients may be identified and followed in some manner.

(b) Each center should establish its own followup system, and justify that system.

(c) The pacemaker center should report periodically on its effectiveness and results.

Private monitoring systems may be appropriate in some areas of the country, and certainly can be well done by some of the systems available. But they are not suitable for every area, and are certainly not suitable for several of the VA hospitals that have superb clinical followup systems of their own. Uniformity of the followup system would destroy these centers, and I believe would drive off some of the best clinicians in the VA.

As I have said in my previous testimony, the most important ingredients of a followup are its existence and its continued implementation, maintenance of the age-old physician patient relationship, and a basic set of electronic tests. The selection of the devices and the test themselves would vary with the academic and geographic makeup of the pacemaker center itself.

Senator Stone. Our next panel is Mr. David M. Link, Director, Bureau of Medical Devices, Food and Drug Administration, and he is accompanied by Mr. Kenneth Baumgartner of the Office of the General Counsel; also, Dr. Seymour Perry, the Director of the National Center for Health Care Technology.

To all of you, we would like to thank you very much for coming this morning, and I invite your opening statements.

A PANEL CONSISTING OF: DAVID M. LINK, DIRECTOR, BUREAU OF MEDICAL DEVICES, FOOD AND DRUG ADMINISTRATION ACCOMPANIED BY KENNETH C. BAUMGARTNER, OFFICE OF THE GENERAL COUNSEL; AND DR. SEYMOUR PERRY, DIRECTOR, NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

Mr. Link. I am David Link, the Director of the Bureau of Medical Devices of the Food and Drug Administration. Mr. Chairman, we appreciate the opportunity to discuss the important subject of pacemakers.

The Food and Drug Administration has a keen interest in pacemakers not only because of the crucial role they play in health care, but because they are representative of many critical life-supporting and life-sustaining devices used in medicine.

As you have requested, we will focus our testimony on three subjects: The value of organizing a pacemaker registry; technical limitations of pacemakers; and the experiences that we know of in the reuse of pacemakers.

If I may, I will just summarize my written statement submitted to you for the record.

Senator STONE. Thank you.

Mr. LINK. Because of the importance of pacemakers in the delivery of health care in what appears to be an unusually large number of recalls, the Food and Drug Administration, in 1974, established a Pacemaker Registry.

This registry is managed by Dr. Michael Billitch, Director of the Pacemaker Center, University of Southern California.

Dr. Billitch is assisted in this project by Dr. Seymour Furman, associate attending cardiothoracic surgeon, Montefiore Hospital in New York, and Dr. Vincent Parsonnet, director of surgery, Newark Beth-Israel Hospital Center, New Jersey.

As you appropriately stated, Dr. Parsonnet is, indeed, in our view, one of the world's experts on the subject, and we are fortunate to have him as a contributor to our registry system.

These three physicians operate major pacemaker centers in the United States and are considered among the world's experts on this subject.

This registry, now, is ongoing and, during the period from July 1974 to December 1979, involved over 4,000 systematically monitored pacemakers.

Its value is that it provides current information on pacemaker performance in a formal and consistent manner. Each pacemaker associated with one of the pacemaker centers is followed from the time it is implanted until the time it is explanted for whatever reason.

In addition, other pacemaker units have come to the attention of center personnel into the pacemaker registry. We view this as providing an additional source of pacemaker experience.

Over the years, information generated by the registry has been extremely useful not only to the FDA but to the medical professions.

It has provided valuable performance information in an unbiased and effective way. While the registry obviously does not include all pacemakers in current use, it includes sufficient numbers to provide both indicative and trend information.

The FDA is expanding its efforts to get timely information concerning problems associated with all devices, including pacemakers.

At present, we are preparing new regulations that will require device manufacturers to report to the agency under certain circumstances defects and deficiencies in their products.

Pacers will be subject to these new reporting requirements.

The elements of data that will be required under this reporting system will include not only the occurrence of the event leading up to the report, but an investigation of the event and any remedial action taken by the manufacturer to prevent its recurrence.

While such a system will not guarantee that all defects relating to medical devices are brought to the attention of the FDA, it will provide FDA with information concerning many events, information that, at present, FDA does not have an effective means of acquiring.

Because all defects relating to devices, including those associated with pacemakers, are not always brought to the attention of the manufacturer, a registry system may provide more information.

Such a system gathers information at the user level rather than at the manufacturer level. The pacemaker registry established by the Veterans' Administration could be a rich source of pacemaker performance data. These data would be valuable not only to professional users of pacemakers within the Veterans' Administration, but to the entire medical community.

Let me go on to some technical aspects of pacemakers. As I mentioned earlier, we are aware that there are problems with pacemakers that, from time to time, require recall.

The fact that these defects exist demonstrates that no product can be designed and manufactured to be perfect at all times. Any product as complicated and sophisticated as a pacemaker that includes a large number of components and is intended to function in he hostile environment of the human body can be expected to fail as a result of random failures of its various component parts.

These random failures can be reduced to a very low level, howver, by rigorous selection, tests, and evaluation.

In our opinion, most failures occur through design and/or manuacturing errors. These two sources of errors can be minimized by igorous and demanding requirements in design as well as manuacturing processes.

Even when problems do occur, however, the consequences are manageable. As in the case of other commercial products whose ailure would be catastrophic, pacemaker designs often include fail-afe features that prevent an unacceptable condition when internal omponents and parts do fail.

Neither pacemakers nor any other manufactured products will ver reach the stage where it can be guaranteed not to fail. Howevr, continuous emphasis on design and manufacturing processes, specially the implementation of current good manufacturing pracces, can produce pacers whose value enormously outweighs the sk and whose performance can be categorized as essentially risk ee.

Upon examining the record of pacemaker performance, a layman ight erroneously conclude that they are not designed and manuctured with the care and rigor they require.

This conclusion would be erroneous. The contemporary pacemakr represents a high state of sophisticated design and manufacturg. Generally, the longevity and reliability of these devices are utstanding.

I have a few comments on the reuse of pacemakers. Because of e considerable cost of pacemakers and because of the technical dvances in their development that have produced pacemakers of considerable longevity, there is, as this committee has noted, a valid question as to their reuse.

Pacemakers may now cost several thousand dollars. They have a normal lifetime of 6 to 8 years or perhaps even longer.

There is, therefore, an understandable concern over the economic waste when a pacemaker is discarded before it has been used to its reasonable maximum capability.

For example, if a pacemaker unit were explanted from a patient who died a year after implantation from causes other than those associated with cardiac problems, it is not unreasonable to ask whether the pacemaker should be used again.

Naturally, there are valid questions relating to cleanliness, sterility, and performance.

To the best of our knowledge, it is not a widespread practice in the United States to reuse explanted cardiac pacemakers. The FDA, therefore, has not developed a specific position concerning this practice.

We understand that the practice occurs in some European countries. However, we have no facts to substantiate these impressions nor do we have information concerning the methods for reprocessing such pacemakers before reuse.

The possible reuse of pacemakers raises issues that are related to another matter in this era of belt-tightening; the question of the reuse of sterile disposable medical products.

The reuse of sterile disposable products has become a practice common in many parts of the United States. However, manufacturers of sterile disposable medical products do not label their products for reuse and, accordingly, give no instructions for processing such devices before reuse.

Because such devices frequently have not been designed for reuse, FDA has stated a formal agency policy that, if reuse is to occur, the user of the device, whether it is a hospital or other medical facility or an individual physician, bears full responsibility for the practice.

In addition, FDA cautions the user—that is, the reuser—of the sterile disposable product that such persons should take steps necessary to demonstrate that, one, the product can be properly cleaned and decontaminated; two, that the product can be properly and effectively sterilized; and, three, that performance of the product is neither compromised nor degraded as a result of the processing.

Senator STONE. Who has that burden under your policy?

Mr. LINK. Pardon?

Senator STONE. Under the policy, is it the person in whom the device is transplanted or is it the hospital or physician that gives it to them?

Mr. LINK. This is the hospital or the physician, the professional person or institution that takes that upon himself or itself.

This policy has obvious potential applications to the reuse of pacemakers. If an institution or organization intends to engage in the practice of the reuse of pacemakers, FDA, because of its responsibilities under the law, certainly is interested in any testing or evaluation and the development of any reprocessing procedures which should be performed before authorizing pacemaker reuse.

Mr. Chairman, this concludes my prepared testimony. If you have any further questions, we will attempt to answer them.

One other thing, Mr. Chairman; I did bring some pacemakers with me, since it is always useful to know what we are talking about.

These are some examples of both older units and contemporary units. I have one more that has been split apart to give some view of its internal composition.

This [indicating] is a newer one which is, as you can see, quite small, with the electronic parts inside. This is an older one.

This older one, of course, has the lead attached to it that goes down into the heart and actually delivers the electrical signal that stimulates the heart. The older one, you can see, has mercury batteries, as opposed to the newer ones that have lithium batteries.

These are by different manufacturers with different configurations, serving essentially the same function.

Senator **Stone**. Do they all use that plastic lead?

Mr. **Link**. They have a plastic top into which the lead goes and through which wires and electrical signals are conducted.

The components inside, the electronic circuitry, is typically hermetically sealed in a sealed metal can.

Senator **Stone**. First of all, I want to welcome you. As I understand it, this is the first time that the National Center and you, Dr. Perry, have testified.

Dr. **Perry**. Correct.

Senator **Stone**. Well, I am very glad to welcome you here, and I hope that we don't turn you off. The purpose of the pacemaker hearing is not to turn them, or you, off.

Do other members of the panel have opening statements?

Dr. **Perry**. Thank you, Mr. Chairman. I would like to just touch on the highlights of my written testimony.

It is always tough to follow a guy who comes in with some props.

It is a pleasure for me to be here today to discuss the role of the National Center for Health Care Technology in evaluating transtelephonic monitoring of cardiac pacemakers.

I want to say at the outset that I am not an authority in this area. I am here to report on the findings of an expert group which was convened by the Center last year.

Because this is the first appearance of the Center before this congressional committee, I would like to begin with a brief description of the Center's mandate and objectives.

The Center was established in November of 1978 by Public Law 95-623, the Health Services Research, Health Statistics, and Health Care Technology Act of 1978.

The Center is located in the office of Health Research, Statistics and Technology within the office of the Assistant Secretary for Health.

Now, one of the primary reasons for creating the Center was to address concerns about the processes whereby technologies are evaluated and applied in the delivery of health care.

It is unnecessary for me to say that, when properly utilized, safe and effective health care technologies can reduce morbidity and increase longevity, offering an advanced quality of life. The appli-

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cation of some health care technologies may, however, produce unanticipated social, ethical, or economic consequences.

Thus, the Center was established to conduct research, demonstrations and evaluations relating to the safety, efficacy and cost-effectiveness of established, new, and emerging technologies and to assess the actual or potential social, ethical and economic impacts.

The Center is neither a regulatory nor a health-care financing agency. Its purpose is to perform or sponsor assessments of high priority health-care technologies. For example, the Center has already initiated, through the assistance of other agencies, assessments of such technologies as coronary bypass surgery, dental X-rays, heart transplants, cesarean section and so on.

Our primary responsibility is to provide results of our assessments and research to those who have need for such information, including the practicing and academic communities, third-party payors, industry and the public.

Through such assessments and the timely release of information, the Center can have a positive impact on the quality of the country's health care, and on the effective and appropriate utilization of technologies.

The Center is the Public Health Service agency which is now responsible for providing, upon request, medical and scientific recommendations to the Secretary for use in setting coverage policy for departmental health-care financing programs. The Center provides advice to HCFA on issues ranging from the appropriateness of both continued coverage for established technologies and coverage for new or, in certain cases, investigative technologies.

As a cardinal principle of policy, these recommendations are based on scientific and medical information derived from the experts in the practicing and academic medical and scientific communities, as well as those in the Public Health Service and other appropriate Federal agencies. In general, HCFA bases its reimbursement decisions on the recommendations from the Center.

The first Public Health Service recommendation regarding coverage of transtelephonic monitoring of cardiac pacemakers was made to the Social Security Administration by the Public Health Service in 1971, when scientifically acceptable clinical data demonstrated the effectiveness of monitoring cardiac pacemakers by telephone.

Prior to 1971, the problem of anticipating pacemaker failure had been very troublesome.

In rendering coverage advice to the Social Security Administration in 1971, the Public Health Service felt that well-working pacemakers could remain implanted after their theoretical cutoff date when many were being removed only because there was fear that they might fail unexpectedly or unnoticed in the future.

It was also found that an outstanding feature of monitoring pacemaker function by telephone lies in the instant accessibility afforded to many patients who otherwise would not be able to visit a physician's office or clinic because of the problems of distance or mobility—a point that several of the experts have already made this morning.

At that time, in 1971, it was determined that transtelephonic monitoring was effective in detecting early malfunctioning of pacemakers and thereby decreasing the proportion of pacemaker failures requiring emergency—as opposed to elective—battery replacement. Most of the pacemakers of that time were powered by the mercury-zinc battery. A schedule for monitoring pacemakers was recommended at that time.

In general, those findings of the Public Health Service in 1971 still hold true today. However, in light of the rapid advances in pacemaker technology over the last 9 years, the Center was asked by the Health Care Financing Administration to review its guidelines for monitoring.

It is important to note that these guidelines are for maximum frequency of reimbursement without requiring special justification, and they should not be confused or equated with guidelines for minimal or optimal medical care.

The Center, with the assistance of the National Heart, Lung and Blood Institute, convened about a year ago a panel of experts in pacemaker technology from various parts of the United States to assist in reviewing the existing guidelines which had been developed in 1971. Several of the individuals who participated at that time—Dr. Parsonnet, Dr. Morris—are present at this hearing. Also represented were experts from HCFA, the Food and Drug Administration, NIH, others from the scientific and medical community, as well as industry.

It was the consensus of the panel at that time that the existing guidelines should be revised in view of the extensive use and experience with the lithium-powered pacemakers and their different and more predictable time for needed replacement. Specifically, the lithium-battery not only lasts much longer than the mercury-zinc battery, but loses power in a gradual and predictable way rather than precipitously.

The vast majority of pacemakers that are implanted now are lithium-powered and relatively few patients have pacemakers that are mercury-zinc powered. For both types of units, monitoring is warranted much more frequently when a pacemaker is first introduced than after the positioning of the catheter and other factors have stabilized so that one is monitoring primarily the stability and gradual exhaustion of the pacemaker.

Senator STONE. The catheter is that plastic lead that Mr. Link held up?

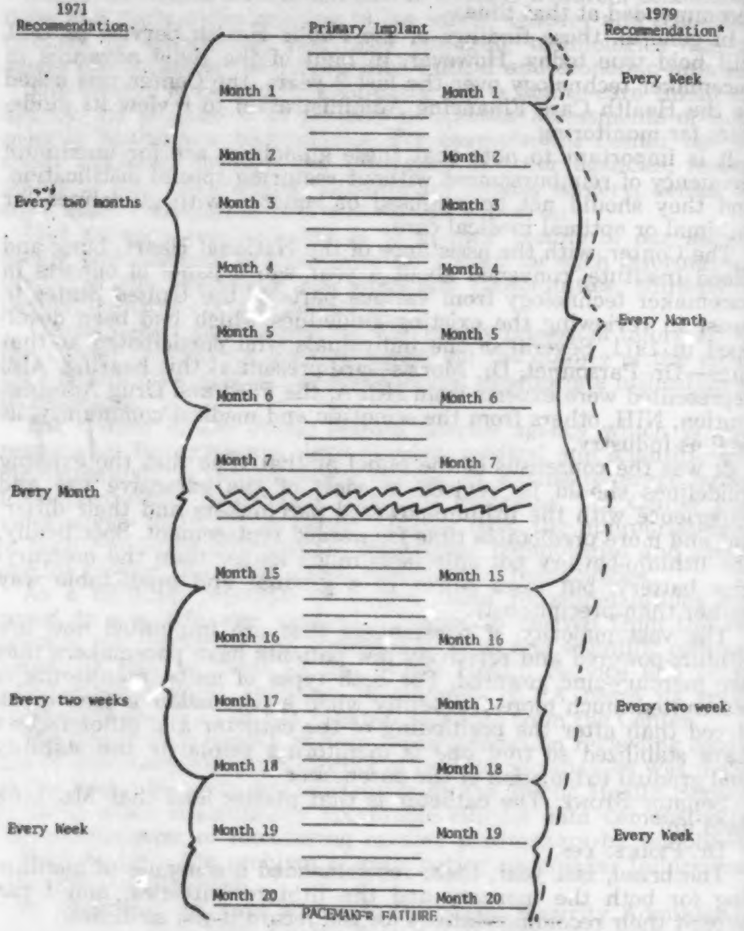
Dr. PERRY. Yes.

The panel, last year, then, recommended a schedule of monitoring for both the mercury and the lithium batteries, and I can submit their recommendations for the record if you so desire.

Senator STONE. That will be included.

[Subsequently, Dr. Perry, Director, National Center for Health Care Technology, submitted the following information:]

FREQUENCY OF MONITORING
CARDIAC PACEMAKER FUNCTION


1971
Recommendation
Primary Implant
1979
Recommendation*
Every Week
Month 1
Month 1
Month 2
Month 2
Every two months
Month 3
Month 3
Month 4
Month 4
Every Month
Month 5
Month 5
Month 6
Month 6
Month 7
Month 7
Every Month
Month 15
Month 15
Month 16
Month 16
Every two weeks
Month 17
Month 17
Every two week
Month 18
Month 18
Every Week
Month 19
Month 19
Every Week
Month 20
Month 20
PACEMAKER FAILURE

LEGEND AND EXPLANATION OF MONITORING CHART

———————— Indicates Mercury Zinc Battery

- - - - - - - Indicates Lithium Battery

*Guidelines recommend weekly monitoring of pacemaker function during first two weeks of implant and pacemaker change without change in lead.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 9, 1979.

Director, Health Standards and Quality Bureau.
Through: Seymour Perry, M.D., Acting Director, NCHCT.
Acting Director, Coverage Assessment Staff, NCHCT.

TRANSTELEPHONIC MONITORING OF CARDIAC PACEMAKERS

This memorandum addresses the subject of appropriate schedules for transtelephonic monitoring of cardiac pacemakers and is intended as a guide for establishing reimbursement policy for the Medicare and Medicaid programs. It is felt that current policies (Coverage Issues Appendix, 10-76) need updating in light of new pacemaker technology—specifically the lithium battery.

In order to assist in development of new schedule guidelines, the Public Health Service, under the aegis of the National Center for Health Care Technology, with the assistance of the National Heart, Lung and Blood Institute, convened a panel of experts in pacemaker technology from various parts of the United States. The consensus of the panel resulted in the following acceptable reimbursement policy.

Lithium powered pacemakers

After Primary Implant (1):	After generator change (2):
q. 1 week × 4 weeks	q. 1 week × 2 weeks
q. 4 weeks after 4 weeks	q. 4 weeks after 2 weeks

(1) i.e., new pacemaker and new pacing catheter
(2) i.e., new pacemaker but pacing catheter not changed

Mercury-zinc powered pacemakers

After primary implant:	After generator change:
q. 1 week × 4 weeks	q. 1 week × 2 weeks
q. 4 weeks after 4 weeks	q. 4 weeks after 2 weeks
q. 2 weeks after 15 months	q. 2 weeks after 15 months
q. 1 week after 18 months	q. 1 week after 18 months

While the panel agreed with the overall schedules as outlined above, one area of discussion is important to note. A slight majority of the experts actually felt that the lithium powered pacemakers, routine monitoring at 8-week intervals was sufficient between 4 weeks and 24 months for primary implants and between 2 weeks and 24 months for generator changes.

In view of the division of opinion at this time, and the recognition by all that for some patients a more frequent interval of monitoring would be necessary, the panel unanimously agreed on the 4-week interval for routine acceptance guidance at this time. It was also agreed that while the guidelines allow for monitoring at 4-week interval represents minimum frequency of telephonic monitoring that constitutes "good medical practice." In fact, it was felt that a majority of practitioners may well choose 8-week intervals during the period in question for many of their patients, and that this choice is perfectly appropriate and does represent "good medical practice."

The opinion was also expressed that as additional data are gathered it may become clear that 8-week intervals are nearly always sufficient for the period in question, or may confirm the wisdom of the current, more permissive guidelines.

Because of the rapidly accumulating information in a field of changing technology, it was recommended that the panel be reconvened in one year's time to reexamine the issue of frequency of monitoring in its entirety.

Finally, the opinion was expressed that more frequent monitoring than even the suggested guidelines may occasionally be justified, based on temporary factors (e.g., a question of a pacemaker malfunction) or on an individual patient's condition, these should be reimbursed if adequate documentation is provided by the practitioner. This position does, of course, represent current policy as stipulated in the Coverage Issues Appendix. It was also noted that a visit to a doctor's office or clinic for checking pacemaker status should be a substitute for, not an addition to, any individual telephonic monitoring episode.

O. B. TOWERY, M.D.

Dr. PERRY. The panel suggested that the guidelines regarding frequency of cardiac pacemaker monitoring be reviewed at least annually, given the complexity of and the rapid pace of development of this particular technology. We expect that such a review will take place this fall under the coordination of the Center, and we would be most pleased to keep the Committee apprised of any recommendations for revision of the guidelines.

Senator STONE. We would appreciate that and request that you do give us any written reports that come out of that reevaluation.

Dr. PERRY. We would be delighted. That concludes my statement, Mr. Chairman.

Senator STONE. Doctor, just one question. Since the criteria that you have established for validating technology for medicare reimbursement has to do with safety, efficiency and effectiveness, being beyond the experimental stage and accepted by the medical community, do you, therefore, feel that the Public Health Service either has determined or will determine that telephonic monitoring meets those criteria?

Dr. PERRY. As far as safety and efficacy——

Senator STONE. Safety and efficacy, being beyond the experimental stage and being accepted by the medical community.

Dr. PERRY. Yes.

Senator STONE. Thank you, Dr. Perry.

Mr. Link, in your testimony, you stated that heart pacers are critical life-supporting and life-sustaining devices.

Is your staff working with any information either statistical or otherwise that might correlate untimely deaths of pacemaker recipients to undiscovered failures in their heart pacers?

For example, you mentioned that an unusually large number of recalls caused the FDA to establish a pacemaker registry.

Mr. LINK. We are continuously trying to collect and gather information, new information, on pacer performance. As I said, the registry that we now have ongoing provides much of that.

The new regulation I alluded to, I think, will generate even more because it will then—or, at that time, when it goes into effect, require manufacturers to report to us events concerning deaths and/or situations where there could be potential deaths or potential injuries.

Senator STONE. When will that regulation take effect?

Mr. LINK. We hope to propose that regulation within the next few months.

Senator STONE. And it will go into the Federal Register, subject to comment?

Mr. LINK. That is correct. We follow a normal rulemaking procedure.

Senator STONE. How many recalls were you talking about more or less?

Mr. LINK. Well, I can only estimate but, over the last perhaps 7 or 8 years, I would estimate we have had at least 15 to 20 recalls.

Now, let me explain as to the nature of these recalls. Since the standards of performance are so high for pacemakers any diminution in performance, when it becomes apparent to the manufacturer or to us, results in a recall. And a typical recall consists of having the manufacturer notify the recipients of the product that performance is something less than ideal so that the doctor, in this case, can, with that information, make a proper determination as to how he should treat any one particular or individual patient.

Senator **Stone**. How many years are we discussing in this ballpark figure of about 15 recalls? Since when?

Mr. **Link**. Seven or eight years, since the early 1970's.

Senator **Stone**. All right. So, then, in the decade of the 1970's, with about 15 recalls, more or less, the proper procedure would be to notify the users and the recipients to come in and get checked, so that it can be found out whether their particular pacer is working up to standards?

Mr. **Link**. Let me describe how we oversee these recalls which are conducted by the manufacturers. We have three purposes in supervising a recall: One, to insure that the manufacturer has, in fact, determined the cause of the defect; two, that he has taken the necessary steps to avoid having that defect occur again; and third most important in this case is insuring that the manufacturer has notified all of his customers.

Now, these customers are either hospitals and/or physicians.

Senator **Stone**. So, it is up to the manufacturer, then, to notify, for example, the VA as a customer?

Mr. **Link**. That is correct.

Senator **Stone**. FDA doesn't notify the VA?

Mr. **Link**. Oh, yes, we do, independently. Whenever we are made aware of a recall, we will routinely notify the VA so that it can do whatever it wants to do with that information.

But, as I say, one of our roles is to insure—and we do this by rigorous inspection of manufacturers' records—that the manufacturer has notified all customers of those suspect products so that the customer can take whatever steps are necessary.

Senator **Stone**. How long does it take a manufacturer to make those corrective responses?

Mr. **Link**. Well, we, needless to say, encourage the manufacturer to do that very expeditiously because the longer the period before the user knows of this information, the greater the hazard a patient, who may have one of these suspect units, is exposed to.

So, we try to insist that the manufacturer notify his customers as soon as possible once all the facts are known.

Senator **Stone**. For a large dispenser, such as the VA, would it be advisable or even necessary to have a current registry so that that kind of recall could instantly or very quickly be communicated?

Mr. **Link**. I would certainly think that having a central repository of all known pacemaker wearers would greatly facilitate a rapid notification to the physicians so that they could do what they feel is proper.

Senator **Stone**. Have you, on occasion, communicated to the VA that it bears the responsibility for possible reuse of pacemakers?

Mr. **Link**. I, personally, was not aware that they were doing it until very recently. I think we have heard that this might be the case. They have not come to us and since we were not aware of their engaging in this practice, we did not go to them.

But if they did say that they were considering this or were doing it, we would certainly advise them as to what we think is important if they are to do this.

Senator **Stone**. What is important?

Mr. LINK. As I said in the statement, it is important to assure, by some rigorous testing, that the product is decontaminated, that, if it is implanted in the body, it is properly and effectively sterilized and that the reprocessing does not adversely affect the performance of the product.

Senator STONE. Does that require sending the device back to the manufacturer for recertification or could that be done by the user?

Mr. LINK. That probably could be done onsite with the necessary equipment and testing procedures. I would certainly think that anybody who was considering doing this would work closely with the manufacturer.

Senator STONE. What kind of equipment is necesary?

Mr. LINK. Well, electronic test equipment so one can measure the output of the signals and insure that the various performance characteristics are, in fact, working properly.

Senator STONE. Now, in your 1976 guidelines, the FDA stated that you have serious questions on whether pacemakers could properly be resterilized because of possibility of body fluids entering the terminal leads of the pacemaker and foreign protein matter risk to the second recipient.

Have you changed that view?

Mr. LINK. I think the current technology which essentially seals the power source and the electronics in a sealed container would make reprocessing more feasible.

We certainly would not decrease our emphasis on careful and rigorous testing to insure that the product was acceptable for reimplantation.

Senator STONE. One last point. You brought your counsel with you, which I thank you for.

In a legal sense, is notification of the second recipient that he might be in receipt of a transplanted device, as opposed to a new one, or an originally used one, a legal necessity?

Mr. BAUMGARTNER. Senator, it certainly raises a product liability question. It is not a legal requirement under the Federal law.

Senator STONE. You heard Dr. Rubin discuss legal advice he had received about the necessity of notifying a recipient of the possibilities of such a transplant and, of course, the lack of a warranty.

Does that enter into your opinion?

Mr. BAUMGARTNER. I'm sorry; I didn't hear the last part of your question.

Senator STONE. The lack of a warranty from the original manufacturer because it is for a second person.

Mr. BAUMGARTNER. Well again, it raises product liability questions but, in the first instance, there has to be a failure before the issue would ever arise. Also, there would have to be some injury to the patient before the issue would arise.

Perhaps, the doctor's counsel was being overly cautious. I don't know. I can't make any further comment.

Senator STONE. I thank you, Mr. Baumgartner, very much and I thank Mr. Link and Dr. Perry for a very helpful panel of testimony. Thank you so very much.

[The prepared statements of David M. Link, Director, Bureau of Medical Devices, Food and Drug Administation; and Dr. Seymour Perry, Director, National Center for Health Care Technology; and

the response of the Food and Drug Administration to written questions submitted by Hon. Alan Cranston, Chairman of the Senate Committee on Veterans' Affairs follow:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PREPARED

STATEMENT

BY

DAVID M. LINK

DIRECTOR, BUREAU OF MEDICAL DEVICES

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

April 23, 1980

Mr. Chairman:

We appreciate the opportunity to discuss the important subject of pacemakers. The Food and Drug Administration (FDA) has a keen interest in pacemakers not only because of the crucial role they play in health care, but because they are representative of many critical life-supporting and life-sustaining devices used in medicine. As you have requested, we will focus our testimony on three subjects: the value of organizing a pacemaker registry; technical limitations of pacemakers; and the experiences of foreign countries in reusing pacemakers.

BACKGROUND

To set the stage for our discussion, I would like to provide the Committee with some basic information concerning pacemakers. The Federal Food, Drug, and Cosmetic Act was amended in 1976 to require that all devices for human use be classified by FDA, based on recommendations of expert panels, into one of three regulatory classes. This is intended to assure that each device will be subject to controls that are sufficient to provide for the safety and efficacy of each product.

-- Class I--General Controls

Class I products are subject only to the general controls which apply to all devices, irrespective of class. General controls include the registration of manufacturers, recordkeeping requirements, labeling requirements, and good manufacturing practice regulations.

-- Class II--Performance Standards

Devices for which general controls are not sufficient to assure safety and effectiveness, and for which enough information exists to develop a standard, are required to meet performance standards established by FDA. Performance standards may specify materials, construction, components, ingredients, labeling, and other properties of the device.

-- Class III--Premarket Approval

All implanted and life-supporting or life-sustaining devices are required to have FDA approval for safety and effectiveness before they can be marketed unless FDA determines that premarket approval is not necessary. Premarket approval can be required of other devices if general controls are not sufficient to assure safety and effectiveness and there is not enough information to establish a performance standard.

The cardiac pacemaker--sometimes referred to as a heart pacer--is an electronic medical device that is designed to stimulate and to pace the heart of critically ill patients. With the aid of this device many thousands of people are able to live productive and comfortable lives. Usually a pacemaker is surgically implanted in the patient's chest. Occasionally however, the device is used externally, for example, during an emergency, or when the patient's condition is being evaluated, or when the physician is determining the suitability of a particular pacemaker for a patient.

Five types of implantable pacemakers are now in use, ranging from the uncomplicated fixed-rate pacemaker to the complex atrioventricular sequential pacemaker. Over 90 percent of pacemakers now in use are the ventricular-inhibited type. This device senses ventricular activity and does not put out a stimulating pulse as long as ventricular activity is normal. Consequently, it conserves battery power. Also, this type of pacemaker will not distort an electrocardiogram.

I have brought with me some examples of modern pacemakers.

Pacemaker Registry

Because of the importance of pacemakers in the delivery of health care and what appeared to be an unusually large number of recalls, the Food and Drug Administration in 1974 established a pacemaker registry. This registry is managed by Dr. Michael Billitch, Director, Pacemaker Center, University of Southern California. Dr. Billitch is assisted in this project by Dr. Seymour Furman, Associate Attending Cardio-Thorasic Surgeon, Montefiore Hospital, New York; and Dr. Vincent Parsonnet, Director of Surgery, Newark Beth-Israel Hospital Center, New Jersey. These three physicians operate major pacemaker centers in the United States and are considered among the world's experts on this subject. This registry now is ongoing and during the period from July 1974 to December 1979 involved over 4,000 systematically monitored pacemakers. Its value is that it provides current information on pacemaker performance in a formal and consistent manner. Each pacemaker associated with one of the pacemaker centers is followed from the time it is implanted until the time it is explanted for whatever reason. In addition, other pacemaker units that come to the attention of center personnel are entered into the pacemaker registry. These units provide an additional source of pacemaker experience. Over the years information generated by the registry has been extremely useful, not only to the FDA but to the medical profession at large. It has provided valuable performance information in an unbiased and effective way. While the registry obviously does not include all pacemakers in current use, it includes sufficient numbers to provide both indicative and trend information.

The FDA is expanding its efforts to get timely information concerning problems associated with all devices, including pacemakers. At present, we are preparing a new regulation that will require device manufacturers to report to the Agency, under certain circumstances, defects and deficiencies in their products. Pacemakers will be subject to these new reporting requirements. The elements of data that will be required under this reporting system will include not only the occurrence of the events leading up to the report, but an investigation of the event and any remedial action taken by the manufacturer to prevent its recurrence. While such a system will not guarantee that all defects relating to medical devices are brought to the attention of the FDA, it will provide FDA with information concerning many events--information that at present FDA does not have an effective means of acquiring.

Because all defects relating to devices (including those associated with pacemakers) are not always brought to the attention of the manufacturer, a registry system may provide more information. Such a system gathers information at the user level rather than at the manufacturer level. A pacemaker registry established by the Veterans Administration could be a rich source of pacemaker performance data. These data would be valuable not only to professional users of pacemakers within the Veterans Administration but to the entire medical community.

LIMITATIONS OF PACEMAKERS

As I mentioned earlier, we are aware that there are problems with pacemakers that from time to time require recalls. The fact that these defects exist demonstrates that no product can be designed and manufactured to be perfect at all times. Any product as complex and sophisticated as a pacemaker that includes a large number of components and is intended to function in the "hostile" environment of the human body, can be expected to fail as a result of random failures of its various component parts. These random failures can be reduced to a very low level, however, by rigorous selection, tests, and evaluation. In our opinion most failures occur through design and/or manufacturing errors. These two sources of errors can be minimized by rigorous and demanding requirements in design as well as manufacturing processes. Even when problems do occur, however, the consequences are manageable. As in the case of other commercial products whose failure would be catastrophic, pacemaker designs often include fail-safe features that prevent an unacceptable condition when internal components and parts do fail. Neither pacemakers nor any other manufactured product will ever reach the stage where it can be guaranteed not to fail. However, continuous emphasis on design and manufacturing processes, especially the implementation of current good manufacturing practices, can produce pacemakers whose value enormously outweighs the risk and whose performance can be categorized as essentially risk-free.

Upon examining the record of pacemaker performance, a layman might erroneously conclude that they are not designed and manufactured with the care and rigor they require. This conclusion would be erroneous. The contemporary pacemaker represents a high state of sophisticated design and manufacturing; generally the longevity and the reliability of these sophisticated devices is outstanding.

REUSE OF PACEMAKERS

Because of the considerable cost of pacemakers and because the technical advances in their development have produced pacemakers of considerable longevity, there is, as this Committee has noted, a valid question as to their reuse. Pacemakers may now cost several thousand dollars; they have a normal lifetime of six to eight years. There is, therefore, an understandable concern over the economic waste when a pacemaker is discarded before it has been used to its reasonable maximum capability. For example, if a pacemaker unit were explanted from a patient who had died a year after implantation, from causes other than those associated with cardiac problems, it is not unreasonable to ask whether the pacemaker could be used again. Naturally, there are valid questions relating to cleanliness, sterility, and performance. To the best of our knowledge it is not a widespread practice in the United States to reuse explanted cardiac pacemakers. The FDA, therefore, has not developed a specific position concerning this practice. We understand that the practice occurs in some European countries. However, we have no facts to substantiate these impressions nor do we have information concerning the methods for reprocessing such pacemakers before reuse.

The possible reuse of pacemakers raises issues that are related to another matter in this era of belt-tightening; the question of the reuse of sterile disposable medical products. The reuse of sterile disposable products has become a standard practice in many parts of the United States. However, manufacturers of sterile disposable medical products do not label their products for reuse and accordingly give no instructions for processing such devices for reuse. Because such devices frequently have not been designed for reuse, FDA has stated as formal Agency policy that if reuse is to occur the user of the device--whether it is a hospital or other medical facility or an individual physician--bears full responsibility for the practice. In addition, FDA cautions the user, that is, the reuser of the sterile disposable product, that such person should take steps necessary to demonstrate: (1) that the product can be properly cleaned and decontaminated, (2) that the product can be properly and effectively sterilized, and (3) that performance of the product is neither compromised nor degraded as a result of the processing. This policy has obvious potential applications to the reuse of pacemakers. If an institution or an organization intends to engage in the practice of the reuse of pacemakers, FDA, because of its responsibilities under the law, certainly is interested in testing and evaluation and the development of any reprocessing procedures which should be performed before authorizing pacemaker reuse.

Mr. Chairman, this concludes my prepared testimony. If you have any further questions, we will attempt to answer them.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PREPARED

STATEMENT OF

SEYMOUR PERRY, M. D.
DIRECTOR
NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

ON

TRANSTELEPHONIC CARDIAC PACEMAKER MONITORING

BEFORE THE

SENATE COMMITTEE ON VETERANS AFFAIRS

APRIL 23, 1980

Mr. Chairman and Members of the Committee:

It is a pleasure to appear before you today to discuss the role of the National Center for Health Care Technology (NCHCT or Center) in evaluating transtelephonic monitoring of cardiac pacemakers.

Because this is our first appearance before this Congressional Committee, I would like to begin with a brief description of the Center's mandate and objectives.

The establishment of the NCHCT was authorized in November, 1978, by Public Law 95-623, the Health Services Research, Health Statistics, and Health Care Technology Act of 1978. The NCHCT is located in the Office of Health Research, Statistics, and Technology, in the Office of the Assistant Secretary for Health (OASH), Public Health Service (PHS).

One of the primary reasons for creating the Center was to address concerns about the processes whereby technologies are assessed and applied in the delivery of health care. When properly utilized, safe and effective health care technologies can reduce morbidity and increase longevity, offering an enhanced quality of life. The application of some health care technologies may, however, produce unanticipated social, ethical, or economic consequences.

Thus, the Center was established to conduct research, demonstrations, and evaluations relating to the safety, efficacy, and cost-effectiveness of established, new, and emerging technologies, and to assess the social, ethical, and economic impacts of these technologies. The NCHCT is neither a regulatory nor a health care financing agency. The principal role of the Center is to perform or sponsor assessments of priority health care technologies. During the next year, for example, the Center plans to initiate, or to collaborate with other agencies in, assessments of such technologies as coronary bypass surgery, dental X-rays, heart transplants, cesarean section and electronic fetal monitoring, renal dialysis and kidney transplantation in end-stage renal disease, and the maternal serum alpha-fetoprotein test in screening for fetal neural tube defects.

Assessments undertaken by the Center would be of little value unless the findings are made available expeditiously to individuals, agencies, and organizations that have need for evaluative information about health care technologies. A primary goal of the NCHCT is to provide high quality information derived from its assessments, evaluations, demonstrations, and research to a broad mix of interested parties, including the practicing and academic communities, Federal agencies with health interests, third-party payers, industry, Congress, and the public. Through such assessments and the timely release of information, the Center can have a positive impact on the quality of the Country's health care and, ultimately, contribute to the containment of health care costs.

Since the inception of the Medicare program in 1965, the PHS has been responsible for furnishing professional advice on health matters, including Medicare coverage determinations, to the Health Care Financing Administration (HCFA) and its primary predecessor agency, the Bureau of Health Insurance (BHI), Social Security

The NCHCT is now the PHS component responsible for providing, upon request, medical and scientific recommendations to the Secretary for use in setting coverage policy for departmental health care financing programs. In carrying out this responsibility, the NCHCT provides advice to HCFA ranging from the appropriateness of both continued coverage for established technologies and coverage for new or, in certain cases, investigative technologies. These recommendations are based on scientific and medical information pertaining to the safety and effectiveness of a technology, and represent a synthesis of the information that is derived from PHS agencies and the practicing and academic medical and scientific communities as appropriate. After considering NCHCT recommendations, HCFA develops coverage instructions for Medicare carriers and intermediaries.

The first PHS recommendation regarding coverage of transtelephonic monitoring of cardiac pacemakers was made to the SSA by the PHS in 1971, when scientifically acceptable clinical data demonstrated the effectiveness of monitoring cardiac pacemakers by telephone. Prior to 1971, the problem of detecting pacemaker failure before the time of total (or clinical) failure had plagued modern medicine. In rendering coverage advice to the SSA in 1971, the PHS felt that well-working pacemakers could remain implanted after the theoretical cut-off date when many were being removed only because of the fear that they may fail unnoticed in the future, thus decreasing the number of operations (and number of pacemakers) required during the lifetime of the patient. It was also found that an outstanding feature of monitoring pacemaking function by telephone lies in the instant accessibility afforded to many patients who otherwise would not be able to visit a physician's office or clinic because of problems of distance or mobility. At that time it was determined that transtelephonic monitoring was effective in detecting early malfunctioning of pacemakers and thereby reducing the proportion of pacemaker failures requiring emergency (as opposed to elective) battery replacement. Most of the pacemakers at this time were powered by the mercury-zinc battery. A schedule for monitoring pacemakers was recommended at that time.

The findings of the PHS in 1971 still hold true today. Monitoring cardiac pacemakers by telephone is effective in detecting early malfunctioning of pacemakers and reduces the proportion of pacemaker failures requiring emergency replacement. However, in light of the rapid advances in pacemaker technology over the last nine years, the NCHCT was asked by HCFA in 1979 to review its guidelines for transtelephonic monitoring of cardiac pacemakers. It is important to note that these guidelines are for maximum frequency of reimbursement without special justification and they should not be confused or equated with guidelines for minimal or optimal medical care. The NCHCT, with the assistance of the National Heart, Lung, and Blood Institute (NHLBI), convened a panel of experts in pacemaker technology from various parts of the United States to assist in reviewing the existing guidelines developed in 1971. Representatives from HCFA, the Food and Drug Administration (FDA), the NIH, the scientific and medical community, and industry participated in the panel deliberations.

It was the consensus of the panel that the existing guidelines should be revised in view of the extensive use and experience with the lithium powered pacemakers and their different and more predictable time for needed replacement. Specifically, the lithium battery not only lasts much longer than the mercury-zinc battery, but loses power in a gradual and predictable way rather than precipitously. The vast majority of pacemakers that are implanted now are lithium powered, and relatively few patients have pacemakers that are mercury-zinc powered.

pacemaker is first introduced than after the positioning of the catheter and other factors are stabilized so that one is monitoring primarily the stability and gradual exhaustion of the pacemaker. Thus, for new implants a weekly transtelephonic monitoring for four weeks would not be unreasonable, or if a pacemaker were replaced but the catheter were not changed, a weekly monitoring for two weeks would not be unreasonable. Thereafter transtelephonic monitoring at four-week intervals would not be unreasonable. Since the mercury-zinc batteries are exhausted earlier and their output declines precipitously, biweekly monitoring after 15 months and weekly monitoring after 18 months were considered not unreasonable. For the lithium powered pacemakers, the four-week intervals seemed reasonable indefinitely. A slight majority of the experts actually felt that for routine monitoring of lithium pacemakers eight-week intervals were sufficient. This only illustrates and reemphasizes that the recommendations are guidelines for carriers for criteria for the maximum frequency of reimbursement without special justification; they were not criteria of minimal or optimal medical care. The panel also recommended that temporary factors, such as questions regarding pacemaker malfunction or an individual patient's condition, may warrant more frequent monitoring.

The panel recommended that the guidelines regarding frequency of cardiac pacemaker monitoring be reviewed at least annually, given the complexity of and rapid pace of development in cardiac pacemaker technology. We expect that such a review will take place under the coordination of the NCHCT, and we would be most pleased to keep the committee apprised of any recommendation for revision of the guidelines.

That concludes my prepared statement, Mr. Chairman. I will be happy to answer any questions you may have regarding the NCHCT's role in providing policy guidance on cardiac pacemaker monitoring.

Response of the Food and Drug Administration to Written Questions Submitted by Hon. Alan Cranston, Chairman of the Senate Committee on Veterans' Affairs

Question 1. In your testimony before the Committee on April 23, you stated that over 90 percent of pacemakers now in use are the ventricular-inhibited type which do not put out a stimulating pulse as long as ventricular activity is normal and, thus, will not distort an electrocardiogram.

A. Can this type of pacemaker be monitored telephonically?

B. If so, is special equipment required in order to monitor telephonically this type of pacemaker?

Answer 1. A ventricular-inhibited pulse generator can be monitored telephonically by placing a magnet, which is provided to the patient, over the pulse generator. This activates a switch within the pulse generator inside the patient and changes the pacing mode temporarily from the ventricular-inhibited mode to an asynchronous mode. This is the normal way in which physicians monitor ventricular-inhibited pulse generators telephonically at the present time.

Question 2. In 1974, the Food and Drug Administration established a pacemaker registry and has had a continuing interest in the technical, life-supporting aspects of pacemakers.

2A. In your opinion, should the proposed VA pacemaker registry be centralized at the national, regional, or medical district level?

Answer 2A. Next, you asked several questions concerning the Veterans Administration (VA) pacemaker registry, based on FDA experience with its own registry over the past six years. Since the apparent purpose of the registries is different, it is difficult for us to answer your questions directly. The purpose of the FDA registry was to see if it is feasible to obtain information from a centralized system concerning pacemaker longevity, failure mode, and failure rate. As we understand it, the purpose of the VA registry is to provide specific monitoring data on each of the pacemaker patients in the VA system. Given that purpose, it appears to be of some benefit to use a standard format for entering data into the VA system so that if there is the need in the future, the data could be collated easily. It also seems, however, that there is no reason to necessarily require that the registry be centralized at a single level (such as the national or regional level).

Question 2B. (1) Could some parts of the VA registry be maintained on different levels?

(2) What are the advantages and disadvantages to maintaining different parts of the registry at different levels?

Answer 2B. Our staff has discussed the FDA registry with representatives from the VA. It appears that there is one potential benefit to the VA of being able to collate data at a central location. It could provide statistically significant information concerning failure modes and rates of various manufacturers' pacemakers, such as the FDA registry has provided over a number of years on a smaller scale. These data could be used by the VA in making decisions on the models of pulse generators the VA would allow to be purchased for implantation. This could take the form of the VA qualifying specific models of pulse generators for implantation in VA hospitals, based on a favorable track record of those pulse generators; or it might provide data which the VA could use to deny the purchase of certain pulse generators when the data show that certain pulse generators are not performing as well as others. However, there seems to be no reason why data in the registry relevant to the status of specific patients could not be maintained at a regional or medical district level.

Question 3. Does the FDA have policy guidelines with respect to the reimplantation of a pacemaker in the same patient?

B. If so, please provide a copy of the guidelines for the record.

Answer 3. You also asked whether the FDA has policy guidelines concerning the reimplantation of a pacemaker in the same patient. FDA has no such guidelines. We have been asked by manufacturers in the past what our policy is concerning the reuse of pulse generators in different patients, as is done in Europe. We have told manufacturers that if they want to sell a pulse generator for reuse, they must provide us with data to show that the pacemaker can be recleaned and resterilized adequately, the labeling must indicate that this is a reused pulse generator, and the manufacturer must be able to predict the expected remaining life in the pulse generator. Under those conditions we would review the data in a premarket approval application with our advisory committee.

Question 4. Please provide for the record a copy of FDA's new regulations that you stated during the hearing "will require device manufacturers to report to the agency, under certain circumstances, defects and deficiencies in their products."

Answer 4. Finally, with regard to FDA's new regulations on mandatory experience reporting, we anticipate that the proposed regulation will be published in the near future. At that time, we will encourage comments from the public before we publish a final regulation.

Senator **Stone**. Our next panel is Mr. John Allen, director of the Pacemaker Diagnostic Clinic of Gainesville, Fla.; Mr. Theodore Stern, the founder of the Cardiac Datacorp, Inc., of Chester Springs, Pa.

I would like to welcome you and thank you both for coming.

A PANEL CONSISTING OF: JOHN ALLEN, DIRECTOR, PACEMAKER DIAGNOSTIC CLINIC, GAINESVILLE, FLA., ACCOMPANIED BY DR. JAMES KENNEDY, DIRECTOR OF OPERATIONS; PHILLIP HOFMANN, VICE PRESIDENT, MARKETING; AND THEODORE STERN, FOUNDER, CARDIAC DATACORP, INC., CHESTER SPRINGS, PA.

Mr. **Allen**. I am the president of Pacemaker Diagnostic Clinic of America, with our main office in Gainesville, Fla.

We are in the business of cardiac pacemaker surveillance on a national level. We monitor patients with implanted pacemakers with a transmitting device that is designed to send certain data over the telephone line to enable us to determine whether or not the pacemaker is functioning according to its specifications.

The information is first reviewed by professional cardiac care nurse before the information is fed into the computer. The computer compares all other previous tests on this particular type of pacemaker and feeds back statistical information for review by our bioengineers and other medical staff, being our physicians.

After a determination has been arrived at, a report is generated and sent to the attending physician for his review and for permanent record.

During these steps, if we should find an abnormality within the pacing system or the patient's heart rhythm, we immediately notify the attending physician by telephone and allow him to perform the most important task, and that is in making the medical decision as to what to do about the patient.

I believe it is important to note that, at no time, do we practice medicine. We are only an extension of the physician's resources that enables him to make a better medical decision.

It has been our philosophy that a pacemaker is a device which was built by engineers and, therefore, an accurate diagnosis of the device would include an engineer's interpretation of its performance along with a proper medical review of the system.

No single physician, unless they are highly specialized in pacemakers such as some of those physicians that have testified today, could be expected to keep abreast of the data changes in technology occurring in the pacemaker industry.

There are approximately 16 active manufacturers of pacemakers in the United States that, cumulatively, offer approximately 130 plus-or-minus models of pacemakers, these being in five major pacing modes using unipolar of bipolar electrodes that pace either the ventrical or the atrium of the heart.

Due to the volume of patients we tested over the past 9 years from all over the country, we have become familiar with almost all of these models and their peculiar characteristics.

The same models may even perform differently in separate patients, therefore setting the precedent that these unpredictable devices should be monitored closely to insure the patient's safety.

I believe the reason that we are here today is for the concern of the veterans with implanted cardiac pacemakers and their safety.

Without going into great detail of the past years' experience with the Veterans' Administration, I would like to comment briefly about our current relationship and what has led me to this witness table today.

In 1975, the Veterans' Administration contacted our clinic to ascertain if we would be interested in providing pacemaker followup service for the Veterans' Administration throughout the Nation.

The background of the VA's position at this time is well documented in the Inspector General's report of February 13, 1980, with specific reference to page 37.

Our company began to actively pursue the VA's proposal in June of 1978 when we were directed by Central Office to the VA Marketing Center in Hines, Ill., to be tested and evaluated by that department.

We were to contact individual medical centers on our own and ask their assistance in evaluating our service with the understanding that we were to bear all the expenses incurred during this period.

The outcome of the evaluation may be summed up by using the words published to all VA installations in its administrative letter dated February 9, 1979. The findings, and I quote:

> Patient and physician acceptance is excellent. The service is easy to use for patient and health care teams. It reduces the time required to perform similar tests in the outpatient clinic. The transmitter is lightweight and compact for placement in a shirt pocket. The service simplifies followup and also enables a physician to keep track of patients some times lost in followup care.
>
> The reports received are extremely accurate, professionally presented, clearly understandable and includes all pertinent information concerning the functioning of a particular pacemaker in a patient.

We were subsequently awarded a decentralized contract effective July 1, 1979 through June 30, 1980.

When we began to solicit business under the contract, we found the seriousness of the situation relating to pacemaker followup at the hospital level in some of the hospitals and reported this to the Veterans' Administration Central Office.

I believe it is important to note at this time that a few of the medical centers have embraced both the letter and the spirit of the Central Office's policy and, consequently, implemented our program.

To the best of our knowledge, through feedback from those hospitals, their followup program is now running very smoothly and efficiently and the physicians and patients are well satisfied with the service they are receiving.

For those medical centers that have not abided by Central Office's policy or that have done so reluctantly, we have encountered and continue to encounter some problems.

The problems are numerous and I will only cite a couple of examples at this point before you.

On a Friday, we tested a veteran who gave us the information that his pacemaker was implanted in October of 1972. And this was in 1979. The information we received from the medical center was inconsistent from the data that we were receiving on this particular test from this patient.

Upon calling the medical center to ascertain the proper information, we were referred to the Chief of Cardiovascular Surgery who assured us that he——

Senator STONE. Where was this hospital?

Mr. ALLEN. This particular hospital was in Brooklyn, N.Y., sir.

To insure that we had our records correct. And he assured us that he would call us right back with the information. This was on a Friday.

On Monday, we again tested the patient's pacemaker and, that time, found that it had no activity whatsoever.

We then called the same physician's office to notify him that the pacemaker had failed. The secretary assured us that he would have the physician return the call within a half-hour. Three hours later, we had to page the physician at the hospital. And when we notified him of the failure, he was concerned so much that the patient had had a pacemaker failure, but wanted to know why we were testing the patients, as all the patients, as he had stated, were being followed by a clinic very close by to the VA hospital; that he could not remember the name of the clinic, that we later found out was owned and operated by this particular VA physician.

He took the information about the patient and failure of that pacemaker and assured us that he would take care of the patient "right away," to quote from him.

Two days later, this physician's secretary called our office and would like the patient's name once again as the doctor had misplaced the information.

Recently, while a VA employee from that institution was attempting to gather data on the patients at that medical center to submit to us to begin to follow those patients, we found that the only place where the information could be located was in the physician's private clinic down the street from the VA medical center. When this employee asked the physician for the information, he was given "one name and nothing more".

There are approximately 100 patients at that VA medical center with pacemakers on which we now have the information. This took us approximately 1 month working with the staff at that VA medical center. And during that period of time, eight of those patients expired.

And it is my understanding that this particular physician was promoted to the position of Chief of Surgery.

Another example and the final example that I would use is, only last month, we received a call from a veteran who stated that he hadn't been feeling well for several hours and his heart was acting up. It was 5 p.m. in the afternoon, and he couldn't reach anyone at the VA medical center.

We tested the patient and he was in ventricular tachycardia and his heart rate was 160 beats per minute. We spoke with his wife, and she informed us that they had no private physician in the small town that they lived in and they did not have any type of insurance coverage, and they were at least 3 hours away from the nearest VA medical center which he went to.

The patient, himself, was not keen on the idea of going to the local hospital's emergency room because of its size.

We advised the wife to have her husband lie down and for her to stay near the telephone for a call from the VA medical center.

Immediately after hanging up the phone, we attempted to contact the chief of cardiology at the medical center. It was 5 in the afternoon and the physician had already left the hospital.

Senator STONE. What state was this in?

Mr. ALLEN. This was Richmond, Va.

We asked the operator to page a cardiologist on duty. At that time, we were given the medical floor which proceeded to tell us that another doctor was on call and they would page that physician. After waiting 7 or 8 minutes on the telephone on hold, we hung up and called back again and were told at that time that the doctor did not even have a pager.

We then asked for the resident cardiologist on duty and reached a physician who stated, "It seems to me that he needs to go to the local hospital." And after persistence with this particular physician, we were finally able to convince him to call the patient as the wife was standing next to the telephone waiting on a call for instructions from the physician to tell them what to do.

The following day, we contacted the VA medical center once again to follow through on the patient. At that time, we found out that the patient had to be taken to the local emergency room and treated. He had to be countershocked in the emergency room and transported to the VA medical center the following day, where he was doing well in a coronary care unit.

At this particular medical center, they had several other patients that live great distances away from the medical center, itself. However, the chief of cardiology, at this time, continues to refuse to abide by the VA's policy by placing those patients on telephonic monitoring.

The list of these could go on as they seem to occur far too frequently. My question is simple: Why is it that we continue to have this tremendous amount of reluctancy with those medical centers that need this type of service the most?

I would like to see implemented immediately some other measures—and Central Office has taken a great number of measures during the past year—to insure that this, indeed, can be implemented at the hospital level.

I think there are other things that could be done at this time and should be done to insure that these patients do not experience some serious difficulty or, perhaps, death in some instances.

Senator STONE. Before calling on Mr. Stern, what things could be done and should be done to help?

Mr. ALLEN. I suppose that the VA has better answers than I do. I know that, from our own experiences with the individual medical centers, we have difficulty, sometimes, in that our clinic and sometimes, and in some cases, myself, personally, seem to be quoted as being troublemakers for one reason or another, which is not the case whatsoever.

We are trying to do a simple job that we were contracted to do.

Senator STONE. In other words, if a pacemaker shows signs of failure, you want something done about it.

Mr. ALLEN. Yes, sir. Exactly.

Senator STONE. In order that the pacemaker will help to keep the patient alive.

Mr. ALLEN. That is correct, sir.

Senator STONE. Thank you, Mr. Allen. I will get back to you. Now, I would like to ask Mr. Ted Stern to give us his testimony. Mr. Stern, I understand you speak from experience.

Mr. STERN. Yes, sir. I have very particular qualifications, Senator.

Thank you for inviting me.

Senator STONE. I would just note to my colleagues and those that are here you have your own pacemaker.

Mr. STERN. I am on my 16th right now.

Senator STONE. Sixteenth pacemaker?

Mr. STERN. Yes, since 1963. So, I'm a rather unusual combination. I'm a patient and I'm rather technically aware of what is going on.

As you said, I am the founder of Cardiac Datacorp. That was the first company in this pacemaker followup business. And it evolved just because of the instances you were talking about just now.

This is not just the VA, by the way. This is generic. This is the kind of thing that happens all the way through the whole system, as far as patient care.

It is much better now. When we first started the pacemaker followup, something like 90 percent of all patients weren't followed at all. They were given a pacemaker and just told to go off.

And it has improved considerably——

Senator STONE. Some did.

Mr. STERN. Some did. And nobody really knew what the modes of failure were; they didn't know how to followup the pacemakers.

And telephone monitoring was a stopgap method. It was arrived at very empirically by saying, "We've got to do something." And it turned out to work very well.

There is all kinds of data showing that we have reduced emergency admissions, and everybody is in favor of telephone monitoring, the people who are experienced.

The problem is that most people who implant pacemakers do not implant a great many. This is not just in the VA system. This is all through the country. There are very few specialists in pacemakers.

Most surgeons or cardiologists who have pacemaker patients, only have a few. So, they have limited experience.

And that—that sort of highlights the need for some sort of centralized care from an expert center. And you cannot point a finger at the VA and say that they are evil. They are following accepted procedures; some guys are better than others.

The idea of surveillance, I think is absolutely essential. Everybody has spoken in favor of it, so I don't want to belabor the point.

And one of the things that permits—that has been missed, totally—we have talked about the number of models of pacemakers, and we are in the new world of lithium. But the people haven't pointed out the fact that there are five different chemistries of lithium batteries and 50 models of batteries used by all the different manufacturers.

Senator STONE. So, there are 150-plus models of pacemakers?

Mr. **Stern**. Using 50 different models of batteries with five different chemistries. First of all, the mode of failure, for each one of them, based on chemistry, has got to be different. The mode of failure based upon manufacturer has to be different. And the mode of failure from manufacturer to manufacturer is going to be different. Then, you combine that with the electronics, and you really have great permutations.

So, the concept of monitoring isn't because people make defective pacemakers; it is because we have such a multiplicity of systems that you are bound to have failures, just looking at plain numbers in terms of reliability; you are going to have failures.

And what you are really trying to do is detect them as early as possible. Hopefully, you will prevent them. But, at least predict them early so that they—you can do something useful for the patient.

If you didn't use surveillance—you know, Dr. Parsonnet has spoken about it. Everybody has spoken about it. If you didn't use surveillance, you would have a lot of problems.

So, let's go on to a few other things. The real personal concern, I think, of the VA is what to do. This IG report has opened up a lot of questions, and you have a choice in terms of monitoring your patients, whether each station could do it, whether you should have a centralized VA station or regional stations or commercial stations.

I don't think the individual station is capable of doing it just because of the volume. There are a few specialized places where they have a high volume but, generally speaking, the average station does not have enough volume to warrant this setup.

Second, even your regional stations have a problem because you have a rotation in personnel. This is inherent in the system.

And we are talking about specialized dedication.

Senator **Stone**. In other words, VA physicians are very often transfered to another VA medical center within a few years?

Mr. **Stern**. Or somewhere else. And then you have lost your continuity. Of course, what we're really talking about here is a very specialized area of medicine, and it is a very small fragment and most doctors are bored with it.

The thoracic surgeon—the smallest part of what a thoracic surgeon does is pacing. To the cardiologist, this is an incidental part, this is the tag end. So, very few people really concentrate on it. But it does require expertise. We talk about all these models and all these modes of failure. Somebody has to really understand these modes of failure and, with the newer ones, with the programability that is coming about, it is very complex.

So, you want people who are specialized. They don't have to know a great deal about a lot of other things, but they sure as heck should know about this part of it.

And, then, you're getting back to your registry thing. The whole medical profession, outside of the VA, has lousy recordkeeping. Everytime there is a recall, it is almost impossible to track the patients. And it is not just the VA. The VA probably has a better record, as bad as it is.

We, as a company, we are following about 10,000 patients right now. We have followed well over 20,000 some. And one of the things we go to whenever there is a recall—we try to assist.

And the manufacturer knows who he sold the pacemaker to but, very often, that patient has gone off to some other doctor. Nobody knows where he is. So, we go track him down.

The VA has a similar problem. If you had a central registry, it conceivably could work out very well but, then, it has to be tied into the dedication.

Senator **Stone**. What dedication?

Mr. **Stern**. The continuity. That is all it is. It is continuity. You cannot leave it to the OR nurse to fill out the warranty card and send it back. Usually, you have to have somebody standing over somebody to get him to fill that part out.

The manufacturers go through incredible pains to get the warranty cards filled out. They really want it done. But it is a nusiance to everybody; nobody wants to bother doing it.

But if you had a routine——

Senator **Stone**. You mean, on a matter of life and death to the patient, he doesn't insist on getting the warranty card in and out and taken care of?

Mr **Stern**. See, you are looking at it retrospectively now. So, you say, "Yes, a recall will occur." But the people who are doing this at the time, they are prepping the patient. They are worried about saving his life now; they are not worrying about the warranty. They figure that's a part of purchasing. And purchasing figures that it is their part. And, then, purchasing in the hospital figures, well, that's central Pennsylvania. Everybody thinks it is somebody else's responsibility. And this would go on in any hospital, too.

We have gone through incredible pains not in the VA system—but we have gone through to the purchasing—we call the doctor. The doctor doesn't know what pacemaker he put in. You might get the manufacturer, but to get the model number or the serial number, forget it. And we go back to purchasing and, hopefully, we get the record from purchasing. And if we don't, then we got—go to the manufacturer. Then, you go in a circle. Then, you finally ask the patient, "Did you get a warranty card?"

Now, if you get this registry, you are not going to automatically create a registry that is going to work. We had a beautiful panel of experts at a meeting about a year or so ago trying to form a pacemaker registry. And the consensus of the whole thing was, "What the hell good is it? It's garbage in and garbage out."

You have this beautiful registry sitting there, and 50 percent of the people won't report to it.

Now, the one way the VA can cope with it—they have the means of doing it—is through purchasing and through centralized purchasing.

I'm not saying that you have to restrict everybody to one model, but I really believe that the art has come to the stage where you could specify parameters, specify type of pacing you want and ask the manufacturer to bid on it, on quantity, and you are entitled to a better price because you are a quantity buyer.

And all this argument about saving money, that's the way to save the money. You will save money in that way, and you will probably get better quality. Approach it in a businesslike fashion.

The manufacturers would like it. It would give them consistency. Their costs are in marketing. They've got to go around and around to everybody. If they had a centralized place to deal with, you'd pick up a lot of advantages, and you would pick up uniformity in quality and uniformity in responsibility and you'd possibly get uniformity in terms of registration of these things.

And as far as the followup is concerned, the VA could have a centralized system not just hospital based because the guys are there, but require that this be a centralized system; buy it, just like you would buy anything else and maintain it or buy it from a company. I would be happy to sell it to you. You know, you are a good customer.

So, you are in a free enterprise system. Let's let the free enterprise system work. Let's have a customer who knows what he wants to buy. Let him look at responsible vendors for the goods whether it's a service or a device and do what we do in any other walk of life. We do it in the military. We do it when we buy cars. We do it when we buy anything.

And I bet it would work very well.

Senator STONE. Thank you, Mr. Stern, very much.

May I ask both of you, gentlemen, and also your associates, how do you evaluate the pacemaker services provided to the veterans by the Florida VA hospitals? I have a special interest in that. I want to hear what you think.

Mr. ALLEN At this particular time, Senator Stone, our knowledge of the three main hospitals—being the Gainesville Medical Center, the Tampa Medical Center and the Miami Medical Center—there are patients at Bay Pines, it is my understanding, and several others there in St. Petersburg.

Presently, Gainesville is utilizing our services as of recently to comply with the VA Central Office's policy on transtelephonic, and they are also doing some in-house clinical followup surveillance.

The Tampa area has had an ongoing program, and I think it is in conjunction with the University of South Florida, where they have had some of their patients on telephonic monitoring for some time now.

The Miami hospital, from the information that we have received and from staff in Miami, did not have a system unless they acquired one recently.

We have been attempting to work with them, and it is our understanding that the chief of cardiology would not speak with us at this time. He says that he will do what he chooses to do and nothing more and refused to talk to us. So, we really don't know exactly what they are doing. But as of a couple of months ago, they did not have a program to my knowledge.

Senator STONE. May I ask both of you how many veterans you estimate have VA pacemakers implanted?

Mr. STERN. I have been trying to estimate that for years and I don't know. Dr. Innes said he estimated 20,000. I thought that was rather high.

You are buying about 3,000 a year, so that would say that yo probably have over 6,000 and maybe 9,000 and it could conceivabl be 20,000. I think that's pretty high, though.

Senator Stone. What do you think, Mr. Allen?

Mr. Allen. Senator, Mr. Hofmann has done some statistica studies from papers that have been published in the World Symposium along with some of the VA's statistics. We don't know a exact number, and I don't think anyone could even be expected t get an exact number, but he has derived a formula whereby we ca give a guesstimate.

Senator Stone. Give us your best estimated guess.

Mr. Hofmann. I am Phillip Hofmann. Mr. Chairman, the VA's AMIS (automated management information systems) Report fo 1978 shows that approximately 8,300 pacemakers were purchased by the Veterans' Administration. That is not to say that those pacemakers were used totally within the Veterans' Administration.

But, as we know, there are sharing service arrangements with various affiliated teaching hospitals where the Veterans' Administration will pay for those cost—pulse generators.

Prior to entering into a contractual agreement with the Veterans' Administration, it was my responsibility to ascertain the total number of Veterans' Administration pacemaker patients who were eligible for our services.

The reason for this was twofold. It was important for our equipment purchasers in the future to plan well in advance and also for the hiring and training of personnel so that we could fulfill our obligations under the contract.

This proved to be a very difficult and, many times, a virtually impossible task. Personnel at individual Veterans' Administration medical centers had little or no knowledge concerning their pacemaker population.

To complicate the matter further, many Veterans' Administration medical centers had entered into these service sharing agreements with affiliated teaching hospitals whereby our veteran patients were referred to these institutions for pacemaker implant and followup and little or no record was transferred back to the referring Veterans' Administration medical center.

As a result of this dilemma, I have recently completed an analysis of the current Veterans' Administration pacemaker population.

To achieve an accurate analysis of this situation, the following sources were used as reference: The AMIS Report for 1978, the Veterans' Administration supply service purchases for 1978, Inspector General's Report 101A-79-42, dated February 13, 1980.

In my prepared statement, I have cited the clinical papers published that I have used to base my statistical data on, and I won't go into those because they are quite lengthy.

But some of these sources cited were the University of Vienna in Austria, the Institution Cardiologia in Italy, Montefiore Hospital and Medical Center, Bronx, N.Y., the Clinique de la Rais, Paris, France, Newark Beth Israel Medical Center and some of the physicians who have published these papers are well known in the field of cardiac pacing: Dr. Escher, Burman, Fischer, certainly Dr. Parsonnet, who has been cited, also.

Senator Stone. Thank you very much.

Gentlemen, both Mr. Allen and Mr. Stern, how do you evalute the compliance of the VA hospitals to the central office directives in following policies for improving monitoring practices?

Mr. ALLEN. Senator, some of the hospitals are complying to the letter of the directives. Then again, there are others of which we have documentation that we would be happy to furnish and we are furnishing central office people at this time of reluctancy among some of those hospitals of complying with the policies.

Senator STONE. The Committee would appreciate having the same information.

Mr. STERN. I really can't tell you, personally, because I haven't been working on that directly. But there is a comment I wanted to make on the reuse of pacemakers, which has been overlooked by everybody.

You can sterilize a pacemaker, but the really vulnerable part of the pacemaker is the connector portion, the part that the lead goes into. And that is where damage occurs during implantation and during removal. It can be abused. You can break the seal at that point.

This is one thing the hospital can't do anything about and the manufacturer would rather rebuild than try to replace and recondition that part.

That is really a vulnerable area. And if you would want to really recycle, you would have to go through tests for hermeticity and everything.

You would probably get away very nicely with a fairly low failure rate, but the legal question would come up. And the manufacturer would not want the responsibility of reconditioning because of that. He would rather rebuild the whole unit. And if the individuals do it, then the legal problem comes up and it is purely a risk factor deciding on—like, the English are willing to risk a few.

Our policy in this country does not allow that. That is the difference.

Senator STONE. Mr. Hofmann, pardon my interruption. Would you complete your estimate?

Mr. HOFMANN. Over a 5-year period, taking into account the AMIS Report and the Inspector General's report and the sources cited, 39,500 pacemakers would have been purchased.

Twelve thousand six hundred of those would have been used as replacement for depleted, failed or recalled units, leaving a patient base of 26,800. Over that same 5-year period, 5,775 of those patients would have died. That would leave a total patient base in 1980 of 21,000 patients.

Senator STONE. Dr. Innes might be accurate in his estimate, according to your study?

Mr. HOFMANN. Yes, sir. I feel that Dr. Innes is quite accurate in his estimate.

Senator STONE. Thank you very much. That is very helpful. We have been struggling to find out the number that we are really working with here.

One last question. Do you think that private contracting services bid out would provide monitoring and central data services at a lower cost than if the VA did it in-house?

Mr. **Stern**. If you put it on a bid basis, with specifications, absolutely. Absolutely. Because there is the economy of the company involved, and an outside source has a built-in data base management system already. So, this would be added on to it.

The VA would have to start up, and then you would have to go right back to this whole business of a dedicated staff that is going to maintain the continuity through the years.

And that is really what you are looking at, the cost in reliability and cost in dollars. The dollars are probably not going to stay the same and, in terms of reliability, you are probably going to lose.

Senator **Stone**. Mr. Allen, is that your view as well?

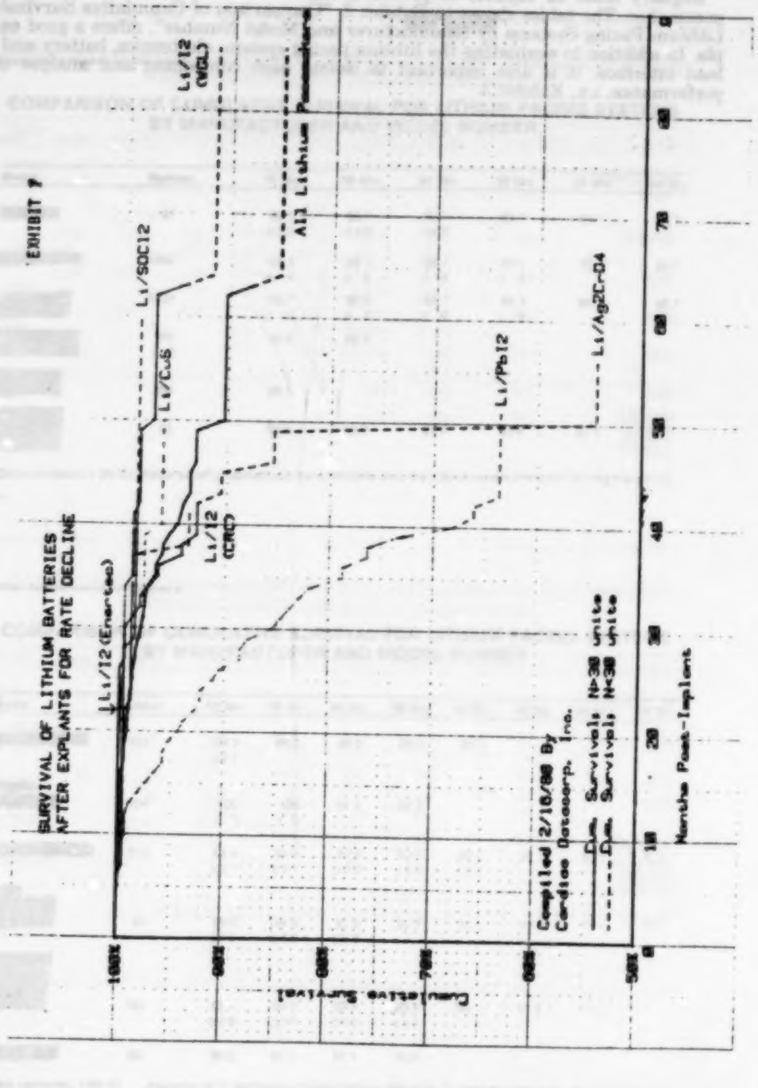
Mr. **Allen**. Yes, sir, I think so. I think it should be put out on bid to other companies. And I don't know that the figures are available. At least, I have not been privy to any recent figures that have come out in comparison of cost of the VA doing it in-house versus contracting services.

However, if everything is being considered on a Federal level to be included into a cost analysis such as we have to do on our profit and loss sheets, for instance, not just taking into consideration whether the physician is here and we need to use him anyway type of attitude but, actually, looking into the cost effectiveness of it, I don't—I do believe it could be performed cheaper when it is put out for bid to companies.

[Subsequently, Mr. Stern of the Cardiac Datacorp, Inc., submitted the following information:]

The performance of lithium batteries varies from manufacturer to manufacturer and model to model, even from the same manufacturer. The attached graph titled, "Survival of Lithium Batteries after Expiants for Rate Decline", (Exhibit 1) presents the 7 manufacturers of lithium batteries by chemistry and shows differences in actual survival. Some of these curves represent as many as 9 battery models, which if analyzed separately also exhibit different survival curves.

EXHIBIT 7


SURVIVAL OF LITHIUM BATTERIES
AFTER EXPLANTS FOR RATE DECLINE
Li/I2 (Enertec)
Li/SOCl2
Li/CuS
Li/I2 (WGL)
All Lithium Powersources
Li/I2 (CRC)
Li/PbI2
Li/Ag2CrO4
Compiled 2/16/88 By
Cardiac Datacorp. Inc.
Cum. Survival, N>30 units
Cum. Survival, N<30 units
Cumulative Survival
100%
90%
80%
70%
60%
50%
0
10
20
30
40
50
60
70
80
Months Post-Implant

Registry must be capable of providing cumulative survival for every model of pacemaker. The tables shown in Exhibit 2, "Comparison of Cumulative Survival for Lithium Pacing Systems by Manufacturer and Model Number", offers a good example. In addition to evaluating the lithium pacing system, electronics, battery and the lead interface, it is also important to isolate each component and analyze their performance, i.e., Exhibit 3.

[redacted]

[illegible]

COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo	42 Mo
[redacted]	87	98.5 ±3.0	96.7 ±4.6	96.7 ±4.6	96.7	96.7	96.7
[redacted]	1662	99.3 ± .4	99.1 ± .5	98.7 ± .8	98.7 ± .8	98.7	98.7
[redacted]	1034	99.3 ± .6	98.9 ± .7	98.7 ± .8	98.5 ± .9	98.7	98.7
[redacted]	100 ± 0	98.9	98.9				
[redacted]	264	99.5					
[redacted]	35	93.9	93.9	93.9	93.9	93.9	

Data compiled 1/26/90 Absence of ± confidence limits indicate less than 30 units at some point during the period

[illegible]

COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo	42 Mo	48 Mo	54 Mo
[redacted]	103	99.0 ±2.1	99.0	99.0	99.0	86.0			
[redacted]	104	100 ± 0	100 ± 0	97.3	97.3				
[redacted]	310	96.8 ±2.1	94.9 ±2.7	93.9 ±3.0	93.2 ±3.3	89.6 ±5.2	82.5	[illegible]	[illegible]
[redacted]	85	96.6 ±4.6	94.8 ±5.8	92.6 ±6.8	90.3	87.5	73.5	73.5	73.5
[redacted]	182	98.4 ±2.8	94.2 ±3.7	93.4 ±4.0	93.4 ±4.0	90.1	77.2	77.2	
[redacted]	20	95.0	87.1	87.1	79.2				

Data compiled 1/26/90 Absence of ± confidence limits indicate less than 30 units at some point during the period

[illegible]

COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo	42 Mo	48 Mo	54 Mo
[redacted]									
[redacted]	256	95.7 ±2.8	92.7 ±4.1	87.7 ±4.9	77.5 ±7.7	62.7	42.0		
[redacted]	4505	99.7 ±.4	97.8 ±.6	96.4 ±.8	94.4 ±1.3	93.7 ±1.6	91.9	91.9	
[redacted]	3218	99.8 ±.4	97.9 ±.6	96.4 ±.9	94.5 ±1.4	93.7 ±1.7	91.8	91.8	
[redacted]	433	98.1 ±1.4	97.6 ±1.6	95.5 ±2.7	94.9	94.9	94.9		
[redacted]	526	99.0 ±.9	99.0	99.0					
[redacted]	204	98.3	98.3	98.3					
[redacted]	121	98.7	98.7	—					

Data Compiled 1/26/80   Absence of ± confidence limits indicate less than 30 units at some point during the period

[illegible]

COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo	42 Mo	48 Mo
[redacted]	687	98.4 ±1.1	97.7 ±1.5	95.0 ±2.2	93.8 ±3.3	91.6 ±4.5	79.3	75.8
[redacted]	56	96.2 ±5.1	96.2 ±5.1	90.0 ±8.7	82.7	82.2	70.1	64.1
[redacted]	34	100	100	95.8	91.4	86.7	86.7	
[redacted]	365	98.5 ±1.5	97.4 ±2.1	96.7 ±2.5	96.7 ±2.5	96.7		
[redacted]	233	99.0 ±1.4	99.0 ±1.4	99.0				

Data Compiled 1/26/80   Absence of ± confidence limits indicate less than 30 units at some point during the period

cardiac data cumulative survival slide 1

COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo.	18 Mo.	24 Mo.	30 Mo.	36 Mo.	42 Mo.	48 Mo.	54 Mo.
[redacted]	35	90.8	81.2	70.4	59.1	59.1	59.1		
[redacted]	286	97.5 ±2.0	97.5 ±2.0	95.7 ±2.8	93.0 ±4.1	91.4 ± 5	91.4 ± 5	91.4	91.4
[redacted]	107	98.9 ±2.1	98.9 ±2.1	95.2 ±4.6	93.6 ±5.5	91.7 ±6.5	91.7 ±6.5	91.7	91.7
[redacted]	56	94.2 ±6.4	94.2 ±6.4	94.2	85.1	85.1			
[redacted]	85	98.6 ±2.8	98.6 ±2.8	98.6 ±2.8	98.6	98.6			

Data compiled 1 26 90 Absence of ± confidence limits indicate less than 30 units at some point during the period

cardiac data cumulative survival slide 2

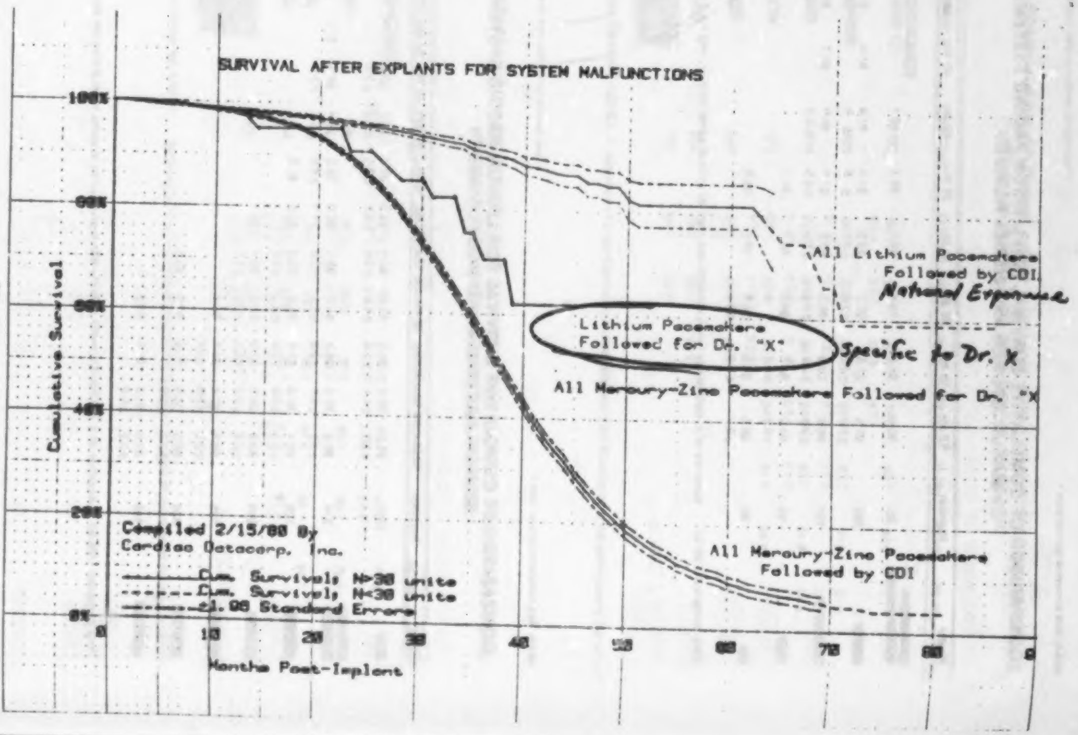
COMPARISON OF CUMULATIVE SURVIVAL FOR LITHIUM PACING SYSTEMS BY MANUFACTURER AND MODEL NUMBER

Model	Number	12 Mo.	18 Mo.	24 Mo.	30 Mo.	36 Mo.	42 Mo.	48 Mo.	54 Mo.	60 Mo.	66 Mo.	72 Mo.
[redacted]	1285	97.2 ±1.0	96.2 ±1.1	94.5 ±1.6	93.0 ±1.8	90.1 ±2.4	88.2 ±3.0	87.1 ±3.5	82.6 ±5.5	82.6 ±5.5	77.4	58.5
[redacted]	314	98.9 ±1.2	97.8 ±1.7	96.2 ±2.3	94.5 ±2.8	93.1 ±3.2	90.0 ±4.1	88.9 ±4.6	86.4 ±5.6	86.4 ±5.6	81.0	61.2
[redacted]	129	98.4 ±2.2	97.5 ±2.8	97.5 ±2.8	96.4 ±3.5	93.2 ±5.6	91.0	91.0				
[redacted]	226	96.8 ±2.3	94.5 ±3.2	93.5 ±3.5	90.8 ±4.7	86.1 ±5.7	86.1					
[redacted]	125	98.3 ±2.3	97.4 ±2.9	94.4 ±4.9	94.4							
[redacted]	306	96.5 ±2.6	96.5 ±2.6	93.5	93.5	87.5						
[redacted]	149	91.5 ±5.2	91.5 ±5.2	91.5	91.5							

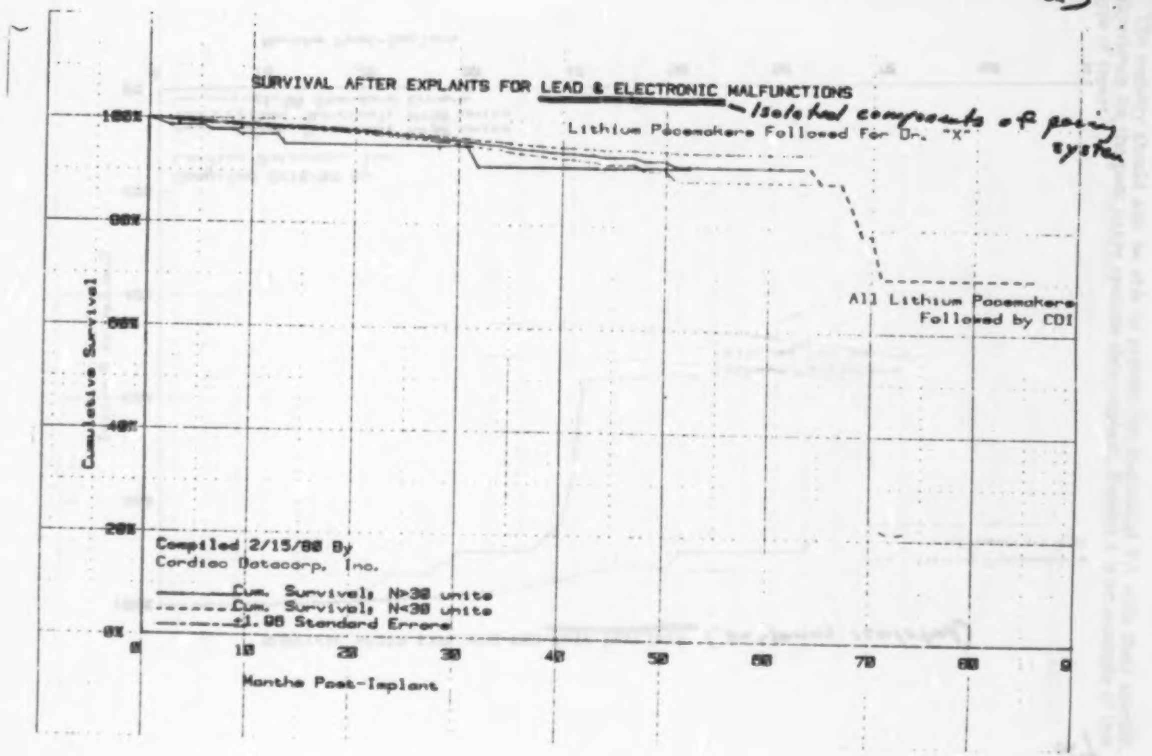
Data compiled 1/26/90 Absence of ± confidence limits indicate less than 30 units at some point during the period

EXHIBIT 3

22

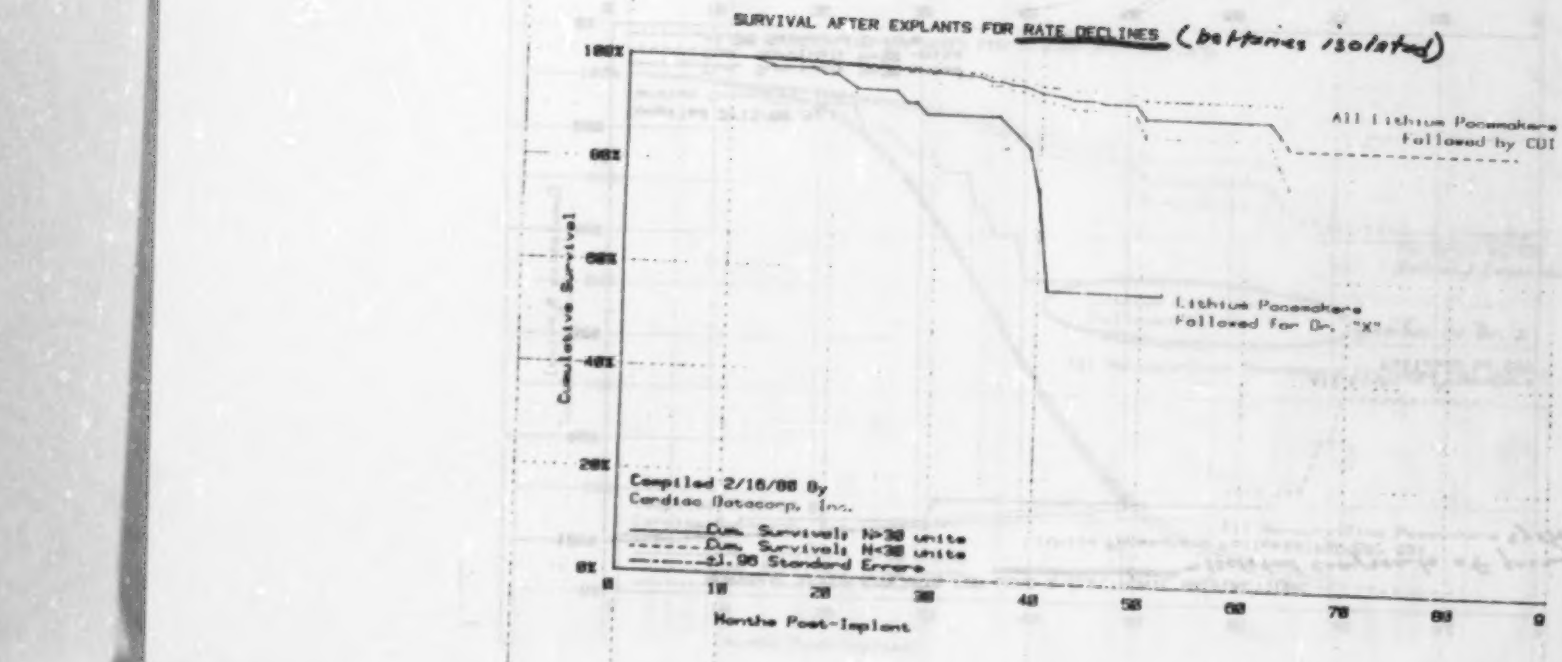

SURVIVAL AFTER EXPLANTS FOR SYSTEM MALFUNCTIONS
Cumulative Survival
100%
80%
60%
40%
20%
0%
0
10
20
30
40
50
60
70
80
Months Post-Implant
All Lithium Pacemakers Followed by CDI
National Exposure
Lithium Pacemakers Followed for Dr. "X"
Specific to Dr. X
All Mercury-Zinc Pacemakers Followed for Dr. "X"
All Mercury-Zinc Pacemakers Followed by CDI
Compiled 2/15/80 By Cardiac Datacorp, Inc.
Cum. Survival; N>30 units
Cum. Survival; N<30 units
±1.96 Standard Errors

23



SURVIVAL AFTER EXPLANTS FOR LEAD & ELECTRONIC MALFUNCTIONS — Isolated components of pacing system

24



SURVIVAL AFTER EXPLANTS FOR RATE DECLINES (batteries isolated)

Compiled 2/16/88 By
Cardiac Datacorp, Inc.

The registry should also be able to provide the individual VA with their specific experience for the pacemaker systems they implant, Exhibit 4 is an example of this type of report.

EXHIBIT 4

CARDIAC DATACORP, INC.

EAST ORANGE VETERANS ADMINISTRATION HOSPITAL
PATIENT HISTORY RECAP

Cardiac Datacorp has monitored 95 patients at East Orange Veterans Administration Hospital. They account for 132 pacemaker implants (mean 1.4 patient); 82 mercury-zinc and 48 lithium powered. The oldest patient is 88 years old and the youngest 50. The average age of patients currently on service is 67.7 years, which is 8 years younger than the average CDI patient.

Currently, 29 patients are being followed by CDI; 2 mercury-zinc and 27 lithium. The mean age for mercury-zinc pacemaker is 33 months and 16.4 months for lithium. East Orange Veterans Administration Hospital's lithium pacemaker systems on the average are 1.4 months older than all other implanted lithium systems being monitored by CDI. The oldest mercury-zinc system functioned for 41 months (Medtronic 5951). Its lithium counterpart is 49 months old (Intermedics 211).

The 132 pacemaker systems comprise 28 models manufactured by 6 companies.

MANUFACTURER	MERCURY-ZINC	LITHIUM
Arco		2
Biotronic	1	
Cordis	4	3
CPI		2
Intermedics		5
Medtronic	9	2
	14	14

The majority of the 35 mercury-zinc explants are for rate decline, 16 (46%), 4 (11%) for electronic and lead failures and 15 (43%) for other explant reasons. The mean age for rate decline explants is 29.8 months, 12.7 months for leads and electronics and 24.6 months for other removals. The breakdown by manufacturer is listed below:

MERCURY-ZINC

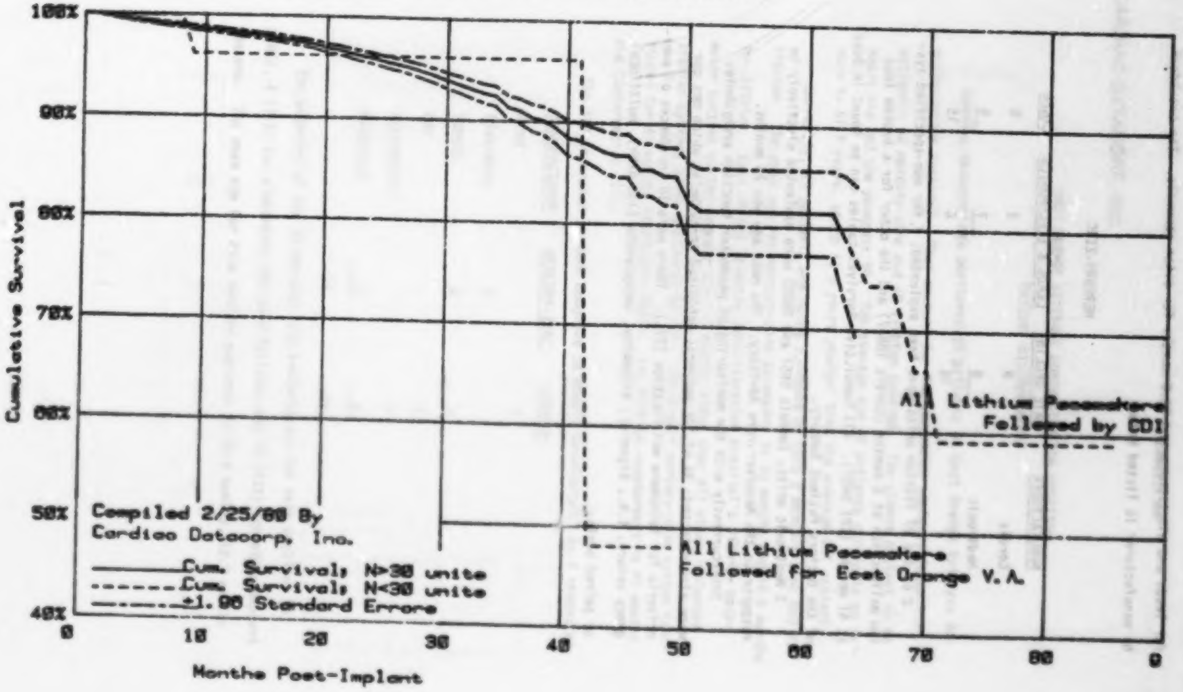
MANUFACTURER	RATE DECLINE	LEADS & ELECTRONICS	OTHER
Cordis	8	3	6
Medtronic	8	1	9
	16	4	15

2 of the 27 lithium units have been explanted; 1 for non-specified system malfunction at 8 months (Cordis 188A7) and the other for a broken lead at 41 months (CPI 0401). All Cumulative Survival tables can be found in back of the Doctors Patient Summary.

2 Medtronic units, (models 5951 and 5950) were explanted electively in response to the Manufacturers Advisory. The mean age was 26 months.

Intercurrently with the monitoring of pacemaker function arrhythmias were also detected; 36 of 132 patients exhibited arrhythmias which met our criteria for telephone notification (27%). There were 10 incidences of emergency nature, i.e., bigeminy, trigeminy, tachycardia (130 BPM+), multifocal or paired beats.

SURVIVAL AFTER EXPLANTS FOR SYSTEM MALFUNCTIONS



Senator STONE. I want to thank all of you gentlemen of the panel.

Do any of you have anything you would like to add?

Dr. **KENNEDY.** Yes. I am Dr. Kennedy, and I would like to point out, initially, that I am not a physician. I am a physicist and electronics is my specialty area, specifically pacemakers.

I would like to add, briefly, to some of Mr. Sterns' remarks. The only way of identifying the failure mode of a particular pacemaker in any of these various models and to identify it in vivo, in the patient, himself, at the time that it is most critical that somebody do something responsive to the problem is to, in fact, do these tests on a large volume of patients so that it is possible to develop groups of each particular type of model and battery of sufficient size that one has statistically meaningful information about that pacemaker.

Senator **STONE.** Is that what a central registry could do?

Dr. **KENNEDY.** A central registry would do this beautifully. This is precisely what a central registry should be doing as one of the many adjunct features that it entailed.

I would add that a central registry or a central service need not—in fact, should not remove the attending physician from the immediate scene of the pacemaker followup.

Telephone service provides technical information about the pacemaker and appropriately applied with the proper engineering backup to interpret the information from the engineering point of view, which is my specialty area, not to exclude the medical interpretation of the telephone work, this is the principal function.

Senator **STONE.** Dr. Kennedy, how would it work? Let's say you were constructing a VA central registry function to accomplish what you have just described. What would you do?

Dr. **KENNEDY.** One scenario would go like this: A patient comes in to a VA hospital, is diagnosed by the staff as requiring a pacemaker, the pacemaker is implanted.

Now, appropriate to the direct medical care of the patient, that VA center is going to continue to maintain direct contact on a clinical basis with that patient over the entire term of that patient's life.

Technical followup by the telephone generally requires more frequent testing than the medical followup, the direct hands-on medical care, that should always be provided by the VA institution.

Senator **STONE.** How does the central registry work in connection with what you have just described as the scenario? Say, there's a telephonic communication now. What happens to it?

Dr. **KENNEDY.** The telephonic communication needs to be entered into this central registry. The information from that also needs to go directly back to the hands of the attending physician and any other physicians that might be directly involved in the patient's care.

Senator **STONE.** You are saying the computer would automatically transmit the information to the physician and it would automatically store it as data in the central computer, is that it?

Dr. **KENNEDY.** That is correct, sir.

Senator **STONE.** What happens to it then?

Dr. **Kennedy**. Now, in terms of direct patient care, the attending physician has this information. He also has a consulting resource with the service, the engineering backup.

He will use that information on a one-for-one basis, in conjunction with his hands-on care of the patient, to provide a total integrated system, under his control, under his supervision, without any threat to destruction of the physician-patient relationship.

Senator **Stone**. Meanwhile, central programing will be accomplished to generalize model performance, and the parameters, the values and the rest of it?

Dr. **Kennedy**. That is correct. In the meantime, there is a central data base coming in from all of the various sources which can be on an ongoing basis subjected to professional, statistical and scientific review to develop product performance information.

Senator **Stone**. Is there anything like this in the country now?

Mr. **Stern**. Yes, we do it, really.

Senator **Stone**. You do it as part of your company work?

Mr. **Stern**. Oh, yes. As a matter of fact, we send back to each physician who will use our service a listing of his patients, the pacemakers they have, and compare the performance of his particular pacemaker population and their pacemakers against the national population.

Senator **Stone**. And that is why you say, since you are doing this commercially, that you or others could bid this kind of service for the VA cheaper than if the VA was to try to set it up itself?

Mr. **Stern**. We have spent 10 years building it up. I think it would take a couple of months, at least, to try to duplicate it.

Senator **Stone**. Well, I thank you very much for clarifying this for me. Thank you all very much.

[The prepared statements of John Allen president, Pacemaker Diagnostic Clinic of America, Inc., and Phillip Hofmann, director for marketing for Pacemaker Diagnostic Clinic of America follow:]

Prepared

STATEMENT OF

ALBERT JOHN ALLEN

PRESIDENT

PACEMAKER DIAGNOSTIC CLINIC OF AMERICA, INC.

BEFORE THE

SENATE OVERSIGHT COMMITTEE ON VETERANS AFFAIRS

U. S. SENATE

April 23, 1980

Mr. Chairman, distinguished members of the committee, it is indeed a great privilege to testify today to what I feel is an important aspect concerning the care of Veterans with cardiac pacemakers.

I am the President of the Pacemaker Diagnostic Clinic of America, with our main office in Gainesville, Florida. We are in the business of cardiac pacemaker surveillance at a national level. We monitor patients with implanted pacemakers with a transmitting device that is designed to send certain data over the telephone lines enabling us to determine whether or not a pacemaker is functioning according to its specifications. The information is first reviewed by a professional cardiac-care nurse before the information is fed into our computer. The computer compares all other previous tests on this particular type of pacemaker and feeds back to us a statistical interpretation for review by our bio-engineers and medical staff. After a determination has been arrived at, a report is generated and sent to the attending physician for his review and permanent records. During these steps, should we find an abnormality within the pacing system or patient's heart rhythm, we immediately notify the attending physician by telephone and allow him to perform the most important task of making the medical decision as to what to do about the patient.

There has been considerable discussion among physicians as to their not wanting someone to tell them how to practice medicine. I believe it is important to note that at no time do *we* "practice medicine". We are only an extension of the physician's resources that enables *him* to make better medicine decisions. It has been our philosophy that a pacemaker is a device which was built by engineers and therefore an accurate diagnosis of the device should include an engineer's interpretation of its performance along with a proper medical review of the system. No single physician unless they are highly specialized in pacemakers such as some of those physicians present today, could be expected to keep abreast of daily changes in technology occuring in the pacemaker industry. There are approximately 16 active manufacturers of pacemakers in the United States that accumulatively offer 130 models, plus or minus, in five major pacing modes using Unipolar or Bipolar electrodes to pace either the ventrical or the atrial. Due to the volume of patients we have tested over the past nine years from all over the country, we have become familiar with almost all of these models and their peculiar characteristics. The same model may even perform differently in separate patients, therefore, setting the precedent that these unpredictable devices should be monitored closely to insure the patient's safety.

I believe the reason we are here today, is for the concern of the Veterans with implanted cardiac pacemakers and their safety.

Without going into great detail of the past year's experience with the Veterans Administration, I would like to comment briefly about our current relationship and what has led me to this witness table today.

In 1975, the Veterans Administration contacted our Clinic to ascertain if we would be interested in providing pacemaker follow-up service for the Veterans Administration throughout the nation. The background of the VA's position at this time is well documented in the Inspector General's audit report of February 11, 1980 with specific reference to Page 37.

Our company began to actively pursue the VA's proposal in June of 1978 when we were directed by Central Office to the VA Marketing Center in Hines, Illinois to be tested and evaluated by that department. We were to contact individual Medical Centers on our own, and ask their assistance in evaluating our service with the understanding that we were to bear all expenses incurred during this period. The outcome of that evaluation may be summed up by using the words published to all VA installations in an administrative letter dated February 9, 1979:

FINDINGS:

"Patient and physician acceptance is excellent. The service is easy to use for patient and health care teams. It reduces the time required to perform similar tests in the outpatient clinic. The transmitter is lightweight and compact with a placement in a shirt pocket. The service simplifies follow-up on patients and also enables the physician to keep track of patients sometimes lost to follow-up care. The reports received are extremely accurate, professionally presented, clearly understandable and includes all pertinent information concerning the functioning of a particular pacemaker in patient."

We were subsequently awarded a decentralized contract effective July 1, 1979 through June 30, 1980. When we began to solicit business under the contract and found the seriousness of the situation relating to pacemaker follow-up at the hospital level and reported this to the Veterans Administration Central Office at that point our difficulties began and continue to exist because of our persistent pursuit to rectify these problems.

I believe it is important to note at this time that a few Medical Centers have embraced both the letter and the spirit of Central Office's policy and consequently implemented our program. To the best of our knowledge, through feedback from those hospitals, their follow-up program is now running very smoothly and efficiently and the physicians and patients are well satisfied with the service they are receiving.

For those Medical Centers that have not abided by Central Office's policy or that have done so reluctantly, we have encountered and continue to encounter problems. As problems are numerous I will only cite a few for the sake of time. I must also note that these problems have been brought to the attention of the officials in Central Office at the time these problems occurred.

Example #1

On August 27, 1979, our Clinic ran a pacemaker test on a 58 year old Veteran that had an implanted recalled pacemaker. The implant date of this pacemaker was March of 1976. The electrocardiogram strip with a magnet indicated a rate of 66.5 beats per minute. This patient had been a part of our Clinical survey performed during our testing and evaluation period from this particular medical center. His last test according to that information was performed in December of 1978 which indicated at that time his 'with magnet' rate was 71.5 beats perminute. Our medical personnel at that point attempted to contact the personnel within the EKG Department of the VA Hospital and the VA operator referred our call to the coronary care unit where they ran the after hour pacemaker check-ups. When we asked to speak to the nurse in charge, their response was "I happen to be the only nurse here". We explained about the patient's test. Told the nurse about the type of pacemaker, the rate, the interval as well as the fact that at the time of his test, he was in his own rhythm in the 'without magnet' strip with his own heart rate being 80 beats per minute. We also stated without having any further information available, we could only report that this patient had had a first cell failure. The nurse's response was simple, "so what". On August 28, 1979, we again contacted this same medical center and asked to speak with the nurse in charge of the EKG department at that hospital. We explained that we were following up on our call of the previous day. We then asked her if his pacemaker had previously been running at 66.5 beats per minute. Her reply was "Never has and it still isn't. It is still beating at 72 beats per minute today". When inquiring how she knew that, she stated that "I called the patient and asked him to check his pulse. It is 72 beats perminute". We then explained to her once again that the patient was in his own rhythm without placing the magnet over the pacemaker. She agreed with this but continued to say "But his heart rate is still 72 beats per minute and was with the magnet too, on the last test". We then asked "When was the last test performed"? Her response, "Not long ago." After having reported twice to the VA Medical Center of the first cell failure, on Wednesday, September 5, 1979, we again tested the same veteran who was still in first cell failure but with an interval increase of 10 milliseconds in one week or a drop of nearly one beat per minute. The patient's wife stated that he had been checked at the VA on August 28, the day after we first reported the first cell failure. His wife said that at that time the VA had told him his pacemaker was beginning to fail and had slowed down. She stated to us that both she and her husband were very concerned especially since he would not be admitted to the VA Hospital until September 24, 1979 for a pacemaker replacement. We then attempted three different times to contact the nurse in charge on the afternoon of September 5, 1979 and had no response. Finally did get in touch with her on September 6 and reported to her at that time the 10 millisecond interval increase. Through our persistance with this patient and with this VA Hospital, we found out two days later this patient had been admitted for a pacemaker replacement.

Example #2

On September 19, 1979 we ran an initial pacemaker test on a veteran with a pacemaker implanted on January 21, 1976. His electrocardiogram with and without the magnet indicated a 'no-output' and his heart rate was as low as 45 beats per minute. The patient's wife told us that the VA had contacted her the day before and told her that her husband would be admitted to the hospital on September 24, 1979 for a new pacemaker. On the 19th, the same day of our findings of the failure, we reported this to the VA and the nurse in charge and suggested due to the mode of failure and the fact that the patient's heart rate was so slow, they might consider bringing him into the hospital a little earlier than rpeviously planned. That same afternoon, we once again contacted the patient's wife to obtain the social security number which had not been placed on our information sheet by the VA Medical Center. We spoke with the patient's sister who stated that his wife was getting him ready to go to the VA as they had decided to admit him today. We asked if she could tell us how long it had been since the patient's pacemaker had been checked. She replied that she could not remember the exact date but it had been longer than six months ago. This particular patient's pacemaker was on a recall list and this had been brought to the attention of the VA Medical Center at the time of our first notification.

Example #3

On a Friday we tested a veteran that gave us the information that he had his pacemaker implanted in October of 1972. The information we received from the VA Medical Center was inconsistent with the data we received from his test. Upon calling the VA Medical Center to ascertain the proper information, we were referred to the Chief of Cardiovascular Surgery who insured us that he would check the records and get right back to us. On Monday we again tested the patient's pacemaker and at that time found that it had no activity. We then called the same physician's office to notify him of the pacemaker failure. His secretary assured us that he would have the physician return the call within half an hour. Three hours later we again called and had to have the physician paged within the hospital. We notified him of the failure and he was not concerned so much with the failure, but wanted to know why we were testing the patient. All the patients were being followed by a clinic close by of which he later stated he did not remember the name. A little later we found out that this same physician owned that particular private clinic. He took the information and assured us that he would take care of the patient "right away". Two days later the physician's secretary called and wanted to have the patient's name again as the doctor had "misplaced it".

Recently, while a VA employee was attempting to gather data on their patients at that VA Medical Center to submic to us to begin to follow those patients, we found that the only place where the information could be located was in this physician's private clinic down the street from the VA Medical Center. When this employee asked the physician for the information, he was given "one name, and nothing more". There are approximately 100 patients in that VA Medical Center with pacemakers on which we now have the information. This took us approximately one month to locate the information due to the uncooperative manner of that particular physician. During that period of time eight patients died. That physician has now been promoted to the position of Chief of Surgery.

Example #4

Only last month we received a call from a vete[illegible]ho stated "That he hadn't been feeling well for several hours and that his heart was acting up." It was after 5:00 p.m. and he could not reach anyone at the VA Medical Center. When we tested the patient he was in Ventricular Tachycardia and his heart rate was 160 beats per minute. We spoke with his wife and she informed us that they had no private physician located in the small town in which they lived. She also stated to us that they had no insurance and they were at least three hours away from the VA Medical Center. The patient himself was not keen on the idea of going to the the local hospital's emergency room. We then advised the patient's wife to have her husband to lie down and for her to stay near the telephone for a call from the VA Medical Center. Immediately after hanging up the phone, we attempted to contact the Chief of Cardiology at the VA Medical Center. It was five o'clock in the afternoon and the physician had already left the hospital. We asked the operator to page the Cardiologist on duty. At that time we were given the Medical floor which proceeded to tell us that another doctor was on call and that they would page that physician. After waiting approximately 7 or 8 minutes on hold, we hung up the telephone, called again, and at that time we were notified that that doctor had no paper. We then asked for the resident Cardiologist on duty and reached a physician who stated "Seems to me that he needs to go to the emergency room there in his home town." We told the physician that the patient had no private doctor nor any insurance to go to the local emergency room in his home town. The doctor then told us "It is not my decision to make." Once again we had to reiterate the fact that this was an emergency situation. The doctor answered reluctantly "Tell him to call me." Once again we emphasized the urgency and asked the physician to please call the patient's wife who was standing by the telephone. We gave the physician the telephone number to call and he finally agreed to do so.

The following day we contacted the VA Medical Center to follow through on the patient. At that time we found out that the patient had to be taken to the local emergency room and treated. He had to be counter shocked in the emergency room and was transported to the VA Medical Center the following day where he was presently "doing well" in the VA Coronary Care Unit. This particular Medical Center has several of their patients that live great distances away from the Medical Center itself. However, the Chief of Cardiology continues to refuse to abide by VA Policy by placing those patients on telephonic monitoring.

The list of those examples could go on, as they seem to occur far too frequently. My question is simple. Why is it that we continue to have a tremendous amount of reluctancy with those Medical Centers that need this type of service the most? The policy is well stated and very specific as to what action should be taken. If the Veterans Administration lives by the quote from Abraham Lincoln, "We care for those who have born the battle and for their widows and orphans", then it is the responsibility of Central Office to see that their policy is implemented immediately at all Medical Centers without further delay before another veteran experiences serious difficulties or perhaps dies.

In further response to your questions, there are a variety of cardiac disorders for which the implanted artificial pacemaker provides the only effective means of therapy. For patients with these conditions the pacemaker has a truly dramatic impact, not only on the health of the patient but also the quality of his life. Nevertheless, like all products of man's handiwork, pacing devices are subject to a number of specific limitations which I will address momentarily. It is most important to recognize that in dealing with the pacer patient one must consider more than just the physical devices themselves. One must consider the entire "pacing system". At the very least the pacing system consists of the pacemaker pulse generator, the wires which conduct the impulses to the heart, the electrodes that transfer those impulses from the wires to the heart muscle, the interface or contact area between the electrodes and the heart muscle, and finally the heart muscle itself. Unsatisfactory performance of any single element in this system will produce a pacing failure.

The pacer pulse generator consists of two principle components. The first of these is the electronic circuitry and the second is the power source or battery. Both of these components have been the subject of important technological improvements which have occurred especially over the past five or six years. While the general effect or this new technology has been to produce a real improvement in device performance and capability. It has like all new technologies, this development has been filled with unanticipated pitfalls. Since 1974 approximately 150,000 pulse generators have been the subject of recalls or product performance advisories, generally instituted by the pacer manufacturers themselves. Where the electronic circuitry is concerned, these recalls and advisories generally have related to the unforeseen impact of subtle aspects of the manufacturing process on the delicate microcircuits employed. Virtually every manufacturer has had a share of these difficulties. It would appear that these unfortunate incidents are, for the moment at least, an unavoidable by-product of the requirement that advances and technology be made available to pacemaker patients before these technologies themselves become obsolete. It must be added that, historically, the bulk of these problems have not led to serious consequences for the patients involved, when they have been dealt with promptly and in an appropriate manner.

There have also been substantial advancements in power source or battery technology over the same span of time; and as with the electronic circuits, the impact of these new battery technologies has been dramatic and very positive. Nevertheless, the performance of some of these products has fallen short of the expectations of the original designers. These problems represent another fraction of the problems which have led to advisories and recalls.

From the point of view of surveillance then, we find ourselves dealing with two opposing forces. On the one hand, we have advances in technology which are leading to real improvements in the performance of pacemaker products and on the other hand we have the continuing probability of specific pockets of problems produced as a result of these new and changing technologies. The improved product performance, where it is in fact real, tends to indicate that the intensity of surveillance can be somewhat less than levels required for earlier products, while the inevitability of additional advisory and recall type problems militates toward some reasonable floor of surveillance activity since it is only through some form of surveillance that problems can be discovered and identified.

Quite aside from the impact of new technologies on surveillance requirements the principle purpose of pacemaker follow-up is to provide each individual patient with personalized surveillance, not on a total range of products but on the one particular specific pacemaker device which he has implanted. Aside from the pulse generator, each of the individual components of the total pacing system listed above represents a potential failure point in this system. The lead wires and the electrode/heart interface are particularly vulnerable parts of the system at the present time. As a result of all of these factors, patients with modern pacing systems can still expect a surgical procedure to revise or replace an inoperative pacing system every two and one half to five years. The recent advent of programmable pacers which permit the physician to non-invasively alter the characteristics of a system, may in fact avoid some of these surgical procedures by permitting the adjustment of a malfunctioning system. However, it is only through diligent surveillance with reasonably spaced evaluations, that the occurrance of system malfunctions can be discovered and identified in an individual patient. Furthermore, it has been shown that such surveillance can when properly applied, be expected to discover problems at an incipient stage so that 85 to 95% of the patients involved will not be conscious of any ill effects at the time the problem is discovered (and presumably corrected). It must be added that while the ability to program some pacemakers will no doubt reduce the number of surgical procedures required to correct malfunctions, it has no impact on the requirements for detecting these malfunctions and in fact places additional demands on the surveillance. The ability to manipulate the characteristics of the pacemakers requires more intense communication between the several physicians frequently involved in a pacemaker patients' care, so that deliberate alterations of the pacer parameters made by one physician are not misinterpreted as pacer malfunction by another.

The Inter-Society Commission on Heart Disease Resources Pacemaker Guidelines have defined the follow-up care or surveillance of the pacemaker patient as having two principle components. The first of these is medical follow-up which is properly left in the hands of the physician and technical people who are experts in the area of pacing and pacemakers. Both of these aspects of follow--up care are absolutely essential in proper management of the pacemaker patient. The role of telephone pacemaker follow-up is principally in the area of technical care. It cannot and should not be used as a complete substitute for hands on physician involvement at the clinical level. It is generally agreed however, that clinical involvement in an individual patient's care can be far less frequent than the technical follow-ups required for good pacer surveillance. As a result telephone represents a very cost effective way of delivering this aspect of care to the patient. By use of the telephone, these routine evaluations can be done from the patient's home or other convenient locations without the requirement of patient travel (which at the present price of gasoline is a significant factor) and without the inconvenience of patient travel since these patients are a typically geriatric population (90% are older than 60 years of age). Telephone follow-up is cost effective further because it removes from the physician and his professional staff and facilities the requirement that they personally be able to accomodate each individual patient at the time technical follow-up is required. This frees them to devote their time and attention to their necessary duties including the clinical aspect of a patient's care. From a patient's point of view, what may have been an hours or day long task getting his pacemaker checked, is relegated to a matter of a few minutes on a toll free telephone line. Added to this is the peace of mind that accrues from knowing ones pacemaker is functioning properly and knowing that if there is ever a doubt they can always reach their follow-up center for reassurance.

The scope of services offered by private monitoring services varies from service to service. For most services the data transmitted include the patient's electrocardiogram and an electronically counted measurement of the pacemaker firing rate. In addition, some services also offer measurements of the pacemaker impulse itself including pulse width and in at least one case pulse amplitude. Some programs involve extensive use of modern computers in the storage, retrieval, and evaluation of pacemaker data. An effective service also has an in-house staff of engineers and scientists who are experts in pacer performance characteristics and problems. This staff forms a consulting resource for the attending physicians who may then rely on the service not only for cardiograms and other data but also for specific engineering information relevent to a given device.

A service which routinely maintains all of its patient and pacemaker data records on a modern computing system has the inherent capability of operating and coordinating a large pacemaker registry system such as envisioned by the current VA policy. Given suitable definitions by the VA staff, such a system can also easily incorporate relevent patient medical information into such a database to provide a comprehensive central registry for both patient and pacemaker information. Since such systems already exist in the private sector, the institution of such programs through these facilities can be affected with a tremendous savings in cost to the Veterans Administration. It can contract for both the physical facilities and the scientific and tecnical expertise, which is already in place, without the requirement of developing these capabilities from ground zero within the VA itself. It is our opinion that a central computer-based transtelephone pacemaker follow-up system provided by the private sector, in conjunction with the VA provided clinical follow-up, coordinated in each applicable institution by the appropriate member of the medical staff is the most cost effective way of delivering cardiac pacemaker monitoring as a complete system to the VA system of some 172 hospitals. Such a system, in addition to delivering the regular routine day to day follow-up data required by the attending physicians, also provides the capability of providing product performance data and recall advisory alerts. It is also a standby resource, 24 hours a day, capable of responding to the need of any VA patient with a pacemaker problem or a suspected problem, no matter which hospital he calls on for care whether the patient was implanted there or not.

Finally, in connection with your request for discussion on the advisability of recycling of pacemakers, it should be observed that the practice of re-use of pacemakers in foreign countries is not wide spread though it is far more common than it is here in the United States. Even in foreign countries there are serious legal and ethical problems which can be encountered with regard to this practice. The pacemaker is generally regarded as an organ of the body and as such subject to the same requirements and constraints placed on the removal of any organ from the body for re-use. Generally this implies that either the patient who is deceased or his next of kin have given consent to the removal of the pacemaker device and, on the other, that the patient receiving the used pacemaker give informed consent with regard to the implant. Where the practice of recycling has been employed in Europe and elsewhere, very stringent guidelines have been established for the selection of the patients to be re-implanted. One critical criteria is that the life expectancy of the patient be shorter than the anticipated remaining life in the pacemaker itself. Subject to these various constraints, the reported success of this procedure suggests that it might have limited applicability under appropriate circumstances in this country and certainly deserves further examination.

PREPARED
STATEMENT OF
Phillip S. Hofmann
Director of Marketing
for
PACEMAKER DIAGNOSTIC CLINIC OF AMERICA
Before The
SENATE OVERSIGHT COMMITTEE ON VETERANS AFFAIRS
U.S. SENATE

April 23, 1980

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

The Department of Medicine and Surgery of the Veterans Administration has long agreed that proper follow-up surveillance of our veteran pacemaker patients is an essential segment of proper patient care. In 1975 a Central Office Pacemaker Committee was established and charged with the development of a Cardiac Pacemaker Registry, the development of a follow-up surveillance system, to insure that all of our veteran pacemaker patients were monitored closely and with the establishment of a stable Veterans Administration policy regarding the speedy implementation of both registry and follow-up system. I submit to you today that these goals have not been reached and that significant progress has not been made. Studies generated by this committee have shown the impracticality of in-house V.A. monitoring systems both on a national and local level. This information has been available for years. The issuance of a multitude of confusing policy statements regarding pacemaker monitoring have resulted in nothing but inaction. The consequences of this inaction have been grave, resulting in a needless loss of life among our veteran pacemaker population and the general public; needless injuries among both aforementioned groups with little hope of improvement in the foreseeable future unless strong affirmative action is taken.

As I will prove in the attached analysis, the Veteran's Administration currently has a pacemaker patient population in excess of 21,000 patients. To date approximately 7,000 patients have been identified. Of those 14,000 lost cardiac pacemaker patients, over 1,000 will die this year....and the Veterans Administration will not know why. If history repeats itself and the V.A. needs 5 years to identify 7,000 patients, these 14,000 lost patients will all die before the task is completed.

How many of our veterans died as a direct or indirect result of pacemaker malfunction? How many innocent citizens died as an indirect result of pacemaker failure in our veteran population? How many of these deaths could have been avoided? These questions are unanswered and will remain unanswered until affirmative efficient steps are taken to correct this situation.

Physicians agree that pacemaker malfunction results in the death of a percentage of the total pacemaker population each year. The exact percentage is debatable. Estimates range from 5% or less to over 20%. Dr. Joseph W. Rubin of the Medical College of Georgia has stated in his work *Permanent Cardiac Pacemakers: Twelve-year Experience with 247 Patients* that two thirds of all deaths in this study group occurred prior to the replacement of the first generator. He also stated that 23% of his pacemaker patients died within 3 years of initial implant. This figure is 13 to 15% higher than the average mortality rate for non-study groups not as closely monitored.

Physicians also agree that pacemaker malfunction will result in the loss of consciousness in a large portion of the total pacemaker population. A survey completed by my company in 1979 found that over 1/2 of our patients were licensed drivers who drove more than once a week. How many traffic accidents resulting in multiple fatalities could have been avoided, and be avoided by proper follow-up surveillance.

The average age of a cardiac pacemaker patient in the U.S. is 66.17 years of age. Falls resulting from loss of consciousness due to pacemaker malfunction cause a variety of injuries in our geriatric veteran pacemaker patients indirectly contributing to their deaths. A study by the Florida Health Care found 65% of geriatric patients with a broken hip died within 6 months of the fracture. These areas are often overlooked when addressing risk associated with cardiac pacemaker failure.

There can be no doubt that the problems faced by the Veterans Administration in this area are grave. Inaction over the past 5 years has resulted in unnecessary death and injury, the lack of a pacemaker registry, the complete loss of contact with the majority of VA cardiac pacemaker patients, alarming exposure to legal redress from inadequately monitored pacemaker patients and confusinn, resentment and hostility at VAMC's regarding VACO policy in this matter.

I submit to you that there exists today an expedicious, efficient, acceptable solution to these problems. It is an accepted fact that the advantages of telephonic monitoring, coupled with routine clinical examination, far outweigh any disadvantages associated with this type of monitoring system. The advent of transtelephonic waveform analysis, combined with computerized data retrieval systems have made an instant nationwide monitoring system available to all of our VA cardiac pacemaker patients. This system is available today and can be implemented in a matter of 120 days or less. It has been tested, evaluated, approved and contracted for by the Veterans Administration Central Office. Veterans Administration purchasing regulations Chapter 8, change 185 dated February 6, 1978 states that VA Decentralized Contracts will be a priority source unless procurement can be effected from:

1. VA excess
2. VA supply department stocks
3. Other government agencies' excess of GSA stock.

Transtelephonic pacemaker surveillance is not available from the aforementioned sources.

I would ask therefore, that in the interest of our veteran pacemaker patients that VAPR general policies be followed and that VA Decentralized Contract be implemented immediately.

ANALYSIS OF V.A. PACEMAKER POPULATION 1980

Prior to entering into a contractual agreement with the Veterans Administration, it was my responsibility to ascertain the total number of Veterans Administration pacemaker patients eligible for our service. This proved to be a frustrating and virtually impossible task. In conversations with various departments of the Veterans Administration, "estimates" varies widely. Personnel at individual Veterans Administration Medical Centers had little or no knowledge of their pacemaker patient population. To complicate the matter further, many Veterans Administration Medical Centers have entered into service sharing agreements with affiliated teaching hospitals whereby, our Veteran patients are referred to these institutions for pacemaker implants and follow-up with little or no record being retained by the referring Veterans Administration Medical Center.

As a result of this dilemma I have recently completed and submitted to Mr. Allen a complete analysis of the current Veterans Administration pacemaker population. This analysis clearly shows that as of April, 1980 there are slightly over 21,000 pacemaker patients within the Veterans Administration health care system.

To achieve an accurate analysis of this situation, the following sources and publications were used as references.

1. AMIS Report of 1976
2. Veterans Administration Supply Services Purchases, 1978.
3. *Life Expectant of Patients Dependent of Age and Indication for Pacemaker Treatment* by Laczkovic, et al. Cardiologic and Surgery Clinic, University of Vienna, Austria.
4. *Computer Generated Survival Curve for Pacemaker and Paced Patients* by Feruglio et al. of the Instituto Cardiologia Udine, Udine, Italy.

5. *How Increased, Logistical, Technical Demands on the Pacemaker Follow-up* Fischer, Montefiore Hospital and Medical Center, Bronx, New York.
6. *Life Expectancy and Survival of 2,262 Paced Patients with Maximum View-back Twelve Years* by Pioger et al, of the Clinique d/Alleray, Paris, France.
7. *Abstract Five Year Follow-up of Permanent Pacemaker Alticenter Study* by Dilitch, Furman, Parsonnet of the University of Southern California School of Medicine, Los Angeles, California; Newark Beth Israel Medical Center, Newark, New Jersey; Montefiore Hospital and Medical Center, Bronx, New York.
8. *Survey of Pacemaker Practices in the United States 1978* by Victor Parsonnet, Newark Beth Israel Medical Center, Newark, New Jersey.
9. *Proceedings of the Sixth World Symposium on Cardiac Pacing*, Montreal, Canada October 2-5, 1979.

For the purpose of Clarity and scope this report is divided into the following sections:

A. Total Veterans Administration Pacemaker Purchases 1975-1979.
B. Allocations for Replacement.
C. Primary Implants 1975-1979.
D. Mortality Rate 1975-1979.
E. Total Veterans Administration Pacemaker Patient Population 1980.
F. Comments.

A. Total Veterans Administration Purchases 1975-1979.

A base of 8,300 of pacemaker purchases is established for 1978 based on the AMIS report that year. By allowing a 5% increase for 1979 and 5% decrease for each preceeding year total purchase 39,508 pulse generators are established for the years 1975 thru 1979.

B. Allocations for Replacement.

31% of pulse generator purchases each year is allocated for the replacement of depleted, failed, or recalled units. From 1975 to 1979, 12,646 units were purchased and implanted as replacements.

C. Primary Implants.

By subtracting total replacements from total purchases a primary implant base of 26,862 is established for the period of 1975 thru 1979.

D. Mortality Rate 1975-1979.

Accumulative mortality rate of 7.5% per year is assumed i.e. of 4,511 patients receiving their first pulse generator implant in 1975, 1,691 or 37.5% will have expired by the end of 1979. Total deaths of Veterans with implanted cardiac pacemaker from 1975 to 1979 are established at 5,775.

E. Total Veterans Administration Pacemaker Patient Population 1980.

By subtracting the total five year mortality figures from the total five year primary implants a total patient population of 21,087 is established for 1980.

F. Comments.

At first glance the base of 8,300 purchases for 1978 seems to be somewhat high but when compared with the Inspector General's report of eight Veterans Administration Medical Centers, the national average, and the total five year picture there can be little doubt as to it's validity.

A recent Inspector General's report of pacemaker implants at eight major Veterans Administration Medical Centers throughout the country found total implants 424 units averaging 53 implants per year of 4.4 implants per month. The Inspector General's report mirrors the AMIS report averaging 4.2 implants per month based on 8,300 units purchased in 1978.

The five year analysis presented in this report establishes the average implant rate of 3.8 units per month in each Veterans Administration Medical Center (to include affiliated teaching hospitals). This rate mirrors the Inspector General's findings. Those established by the AMIS report for 1978 and the United States national average of 3.2 implants per month in 2,515 U.S. hospitals.

The slightly higher implant rate for Veterans Administration Medical Centers as compared to the National Average is due to the following factors:

1. Veterans Administration Medical Centers have virtually an all male population. Males have a higher incident of cardiovascular disease than do females.
2. Veterans Administration Medical Centers have virtually no pediatrics or adolescent patient population this increasing the average age of the patient base.
3. The average age of a pacemaker patient in the United States is 66.7 years. 82% of all pacemaker patients are 61 years of age or older.
    - a. All of our World War I Veterans are in this group.
    - b. Any World War II Veteran 24 years of age or older at the beginning of World War II is now in this group.

Senator **STONE**. Now, for our final witness, Dr. W. J. Jacoby, the Deputy Chief Medical Director of the Department of Medicine and Surgery of the Veterans' Administration, accompanied by Mr. Robert Coy, Deputy General Counsel.

TESTIMONY OF DR. W. J. JACOBY, DEPUTY CHIEF MEDICAL DIRECTOR, DEPARTMENT OF MEDICINE AND SURGERY, VETERANS' ADMINISTRATION, ACCOMPANIED BY ROBERT COY, DEPUTY GENERAL COUNSEL; CLYDE COOK, DIRECTOR, SUPPLY SERVICE; AND DR. ROSS FLETCHER, CHIEF OF CARDIOLOGY, VA MEDICAL CENTER, WASHINGTON, D.C.

Dr. **JACOBY**. Good morning, Senator.

Senator **STONE**. Good morning, and thank you so much for coming. I'm very pleased you've been here to hear everybody's input.

Now, in addition to your own prepared remarks, please feel free at this time to comment on anything you have heard, whether you agree or disagree. Then, of course, we will get into some questions and answers.

Dr. **JACOBY**. Senator, before I begin, I would like to introduce Mr. Clyde Cook who is on my far right, the Director of the Supply Service in central office. Mr. Robert Coy, next to me, you recognize. Also, Dr. Ross Fletcher on my left is the Chief of Cardiology at the Washington, D.C., VA Medical Center.

It is certainly my pleasure to be here today to provide an overview and analysis of the Veterans' Administration cardiac pacemaker program.

I would request that our formal statement be entered into the record.

Senator **STONE**. It will be done.

Dr. **JACOBY**. As we review the historical perspectives, the current status, and the VA's future plans with regard to our policies for providing quality care to those patients requiring cardiac pacemakers, we should bear in mind that the VA is a leader in this area.

And I would call your attention, Senator, that some of your panelists also pointed that out.

It is the only health-care system within the United States that has addressed a cardiac pacemaker program on a national basis.

It has developed some unique and comprehensive approaches to resolving many of the major problems that are associated with this issue.

We trust that this testimony and supporting documentation will lead to a more complete understanding of the VA's role in this regard.

The first cardiac pacemaker was implanted in a patient in the 1950's and, since that time, the Veterans' Administration has participated in the development and use of cardiac pacemakers in this country.

As a point of fact, the first lithium-powered cardiac pacemaker—excuse me—the first nuclear-powered cardiac pacemaker was implanted at our VA medical center in Buffalo, N.Y., in the early 1960's.

The VA's original pacemaker implantation program grew slowly. During this time, the Inter Society Commission for Heart Disease

Resources was established and developed the state of the art guidelines in the field of cardiac pacemaker nomenclature, implantation and followup.

Along with their colleagues in the communities and universities, VA has generally followed these guidelines.

As the number of pacemakers and complexity of pacemakers increased and with the increasing number of VA patients becoming pacemaker recipients, the VA felt the need to develop a systemwide policy in this area.

The first step in the development of our policy was the creation in 1975 of a VA Central Office Pacemaker Committee to assist in the management of this program.

The committee was composed of physicians and biomedical engineers.

Senator, I might comment on the question raised earlier regarding biomedical engineers. The VA, in the central office and in the field, have biomedical engineers, as part of its permanent staff.

The committee also composed staff administrators and they were charged with keeping abreast of developments in this field with collecting data on VA pacemaker activities and with establishing a pacemaker registry to identify and monitor the total VA cardiac pacemaker population and with developing a formal comprehensive VA policy encompassing the many variables in the cardiac pacemaker field.

The VA's overall position on cardiac pacemaker prostheses was established in D.M. & S. Circular 10-79-269. This circular addresses implantation in veterans who require such devices, followup of the veterans, collection of data about cardiac pacemakers and the establishment of cardiac pacemaker prostheses referral (CPPR) centers.

Several of the physicians' testimony and, also, the corporation's testimony discussed the center concept. They also talked about it being a regional concept.

As you know, Senator, from our prepared statements, ours is not only a regional, it is a district concept followed by a regional concept, followed by a national concept.

I submit that this is a very well-thought-out, well-organized system for cardiac pacemaker monitoring.

It is our policy that permanent cardiac pacemaker prostheses will be implanted and replaced only in the CPPR centers.

So, this restricts, then, the number of hospitals where we will implant permanent cardiac pacemakers.

Senator STONE. How many?

Dr. JACOBY. At the present time, there are approximately 90 CPPR centers of our 172 hospitals.

The circular reaffirms our commitment to provide eligible veterans who have cardiac disease requiring cardiac pacemakers with prostheses of the highest quality, and requires that administrative review and the professional supervision of such patients will be accomplished and documented.

This circular and other VA directives reflect not so much a modification of VA policy, but a reaffirmation, as previously mentioned, of an acceptable medical practice that has existed in our medical centers. Followup surveillance or monitoring of cardiac pacemakers can be accomplished in one of three ways. And, again, this was stressed by each of the panelists, I think, that have appeared here this morning.

The first technique is direct clinical surveillance which is the evaluation of the patient. There is absolutely nothing which supplants the evaluation of the patient, looking at the patient as a whole, rather than as a mechanical device which is driving his heart. Direct clinical evaluation is still the foremost way of evaluating a patient with a cardiac prosthesis.

The second is by remote telephonic surveillance, and third is by a combination of these methods. And Senator, it is the VA's policy that the combination of both certainly achieves, in many cases, in many patients, the ideal. But this final decision must rest with the physician who is caring for the patient as to how among these three approaches he monitors the patient.

This is based, of course, on the clinical status of the patient. Since telephonic monitoring has assumed such importance in the followup of care of pacemaker recipients, we have been extremely interested in exploring the full capabilities of our existing in-house and private sector systems.

The VA medical center in San Francisco, for example, began a VA central office sponsored in-house surveillance activity in 1976, and has a comprehensive program operating in Medical District No. 27.

Insofar as private sector telephonic monitoring capabilities are concerned, the VA operating center in Hines, Ill., has thus far tested cardiac pacemaker services from five private sector companies.

The first to gain approval was Pacemaker Diagnostic Clinic of America, of Gainesville, Fla. We are initiating a study to compare the efficacy, cost effectiveness and quality of some of our VA medical center-based telephonic surveillance programs with several of these available in the private sector.

The completion of this study should produce results with clinical as well as economic import to the VA.

I have to submit that, at the present time, neither the private corporation nor the VA can say which is the cheaper method. This study needs to be done.

As part of the policy of cardiac pacemaker prostheses, the VA implemented procedures to establish an automated registry. They were established at each medical center with a central registry in VA central office.

The purpose of the registry is to provide continuous overview of such patients to furnish information for improving the quality of care rendered to all pacemaker recipients and to detect possible defect trends occurring in implanted cardiac pacemakers.

I can only stress that our registry will accomplish exactly what has been submitted by several of the panelists, again, this morning. It would certainly be a great help to the FDA, as well as helping us to identify our patients at times for such things as recalls.

The VA has no centralized contract for procurement of pacemakers or related items. Past procurement has been by means of individual medical center contracts and by use of a known mandatory Federal supply schedule.

Manufacturers of pacemakers or their representatives have been contacted to obtain a show of interest in entering into a possible centralized contract with the VA for cardiac pacemaker prostheses and related items. All major manufacturers contracted are interested in pursuing such a contract.

Arrangements could prove it to be more cost effective, more responsive to VA needs and would assist the VA in providing greater control of its pacemaker programs.

For many years, the VA has utilized the Food and Drug Administration's regular recall notification procedures to inform all of its medical centers about the device identification as being defective.

In January of 1980, the VA marketing center began issuing a monthly recall summary. This publication is used as a checklist to assure that corrective action has been taken concerning previously announced recalls and field corrections by FDA, as well as the VA marketing center suspensions.

I would be less than candid if I attempted to down play the VA's concern about the entire pacemaker monitoring issue.

We are working with defined policies and with organizational structures and interpersonal relations that must be considered when this issue is discussed.

However, it is important to note in this field, as with many other medical care activities, there is a subtle yet complex interrelationship between providing centralized guidance to field activities and encouraging appropriate local judgment.

We are still faced with the perception on the part of many of our medical center physicians that attempts are being made to dictate the kind of health care that they should be delivering to their cardiac patients.

This is a serious matter, but I am happy to say that progress has been made in alleviating many of the concerns because of the major efforts of our medical and administrative leadership.

I would anticipate that, with continued experience and with existing policies and with a wider selection of available in-house and vendor monitoring programs, further concerns in this regard will be resolved.

In summary, the VA's cardiac pacemaker program is operating under defined policies and procedures and is employing both in-house and commercially available technology to further the goal of providing the best possible patient care to cardiac pacemaker recipients.

Although we have come a long way in the cardiac pacemaker field and now have a formal program which is balanced, flexible and appropriate to our decentralized concept of health care delivery, what remains to be done will be done.

Mr. Chairman, this concludes my presentation, and I would be pleased to answer any questions.

Senator STONE. Thank you, Doctor.

Before going on to questions, the assistant majority leader, the Chairman of our full Senate Veterans' Affairs Committee, is here and has a statement.

Senator Cranston?

Chairman CRANSTON. Thank you very much, Dick. I appreciate the opportunity to be here. I am sorry I didn't hear your full testimony, Dr. Jacoby, and that of others, but I assure you that we will examine it very carefully and pay heed to what you have said to us. I wanted to welcome the witnesses that are here and others present for this hearing.

I also want to thank you, Dick, for your very hard work to make sure that veterans who rely on the VA for the proper functioning of cardiac pacemakers receive comprehensive monitoring and related health-care services. You are to be congratulated for calling attention to this most important problem and for taking the initiative in this very important area.

Because of the number of implantations performed by the VA and the number of veterans with pacemakers who are eligible for VA health-care services, I share your view, Dick, that the time has come for the VA to implement systemwide policies for procurement, implantation and monitoring of pacemakers that recognize adequately and with flexibility the rapid rate of change of both the development of cardiac pacemakers and monitoring technology.

I believe that the designation and establishment of the cardiac pacemaker prostheses referral centers in each of the 28 VA medical districts to implant, treat, and monitor veterans with pacemakers is truly a major step toward assuring improved coordination of this program throughout the VA health-care system, which should result in the improvement of care to those veterans. Also of great importance is the assurance of comprehensive pacemaker registries.

I am grateful to Senator Stone for his effort and outstanding leadership in this area, as I know many, many veterans who will benefit from his work and their families will be grateful. I am sure today's hearing will provide the committee with valuable information to enable us to effectively follow the development and operation of the VA pacemaker program. I intend to continue the monitoring of the area very actively myself, working closely with Senator Stone. I will be submitting some questions for the record, but I will not offer any verbally at this point.

Again, I thank you, each and all of you, and I thank you, Dick, very much for your good hard work on this.

Senator STONE. Thank you, Mr. Chairman. We appreciate your leadership on the committee and in this area.

Dr. Jacoby, according to the Inspector General's report, 14 veterans at the VA medical center in Minneapolis were given pacemakers that came from the deceased bodies of other veterans after these pacemakers had been sterilized at the hospital. Is that an accurate number?

Dr. JACOBY. To my knowledge, Senator, that is accurate.

Senator STONE. Has the VA ever notified those 14 patients or their survivors or family members that they had received previously used pacemakers?

Dr. JACOBY. Senator, I am not aware if they have notified those families. I can't say in a positive fashion for you.

Senator STONE. Will you answer that question for the record?

Dr. JACOBY. I would be most happy to get that information submitted for the record, Senator.

[Subsequently, the Veterans' Administration submitted the following information:]

VAMC Minneapolis, Minnesota, where the implantations in question occurred, did not notify the patients or their survivors or family members that they had received used pacemakers. We are writing to the medical center director and advising that patients should have been informed about the implantation of used pacemakers. In that connection, we will recommend that consideration be given on a case by case basis to providing notification now. We will recommend that in light of the lapse of time (ranging from four to 28 months) since implantation and the age and general health of these patients, that decisions on notification be left to the individual physicians. Where patients will not be notified, the failure to so notify and the reasons for that course will be noted in the patient's records.

Senator Stone. Thank you, sir. The Chief Medical Director said, in response to the Inspector General's report, that used pacemakers will not be recycled for other veterans at VA hospitals because of the negative public relations impact of doing it.

Has this been adopted as the official policy of the VA?

Dr. Jacoby. Yes, it has, Senator. The policy of reuse of pacemakers was discontinued, and there have been no implantations of pacemakers previously utilized in patients since January of 1980.

Senator Stone. Have you done any followup studies to determine whether used pacemakers were as safe as the new ones and, if so, what did you find?

Dr. Jacoby. Senator, I don't believe that those studies have been done. It is certainly a problem which is receiving consideration.

As you heard this morning, this has been an area of great interest and there are varying views, particularly from a technical standpoint, a legal standpoint, not so much from a true medical standpoint.

Senator Stone. How many veterans, now alive, are wearing pacemakers which were implanted at the VA hospitals?

Dr. Jacoby. Senator, at the present time, we are gathering that data. As I mentioned in my testimony, we are setting up a registry.

The results that we have had forwarded are at the present time, being computerized. We have now in the nature of some 20,000 statements which have been submitted to us. We are trying to get data back to 1963.

This material will be submitted to the computer, and I think that we would have some accurate data in approximately August or September of this year from this initial data survey.

I have some preliminary information at the present time that there are some 7,681 patients with pacemakers being followed in the VA medical centers. Now, of course, there are patients that have had pacemakers implanted at a VA hospital and then may have returned to their private physicians. There are patients who were implanted elsewhere, and they came in for followup in the VA center.

So, it's a question that I think we are going to have to go back to our computer data, and I think we can come back out at that time with some fairly accurate numbers, rather than taking three or four sources of information and arriving at a number which I don't think, fundamentally, has any value whatsoever.

Senator Stone. Will you be able to supply the committee with that by September?

Dr. Jacoby. We will certainly try, Senator. That is our goal.

Senator Stone. How many do VA hospitals now implant each year?

Dr. Jacoby. I would say approximately 3,000 pacemakers per year. Some of these, of course, may be reimplantations.

Senator Stone. Last fall, in response to my questions to the VA, your office said that you were setting up a computerized record system to keep track of veterans wearing pacemakers.

More recently, I have been told that it is not working to date. When do you think you will have this system ready?

Dr. Jacoby. Senator, that is the material that I referred to as the registry; the initial information has been gathered, and it has been submitted, as I mentioned, for computerization.

Senator Stone. What methods are you now using to monitor the safety track of veterans that are wearing pacemakers?

Dr. Jacoby. At the present time, Senator, we are using one of three techniques: One, that the physician is evaluating the patient personally; two, that of telephonic evaluation of the patient; or, three, a combination of both techniques.

Senator Stone. If clinical monitoring is the best, as you have described, how will the VA accomplish this when its outpatient clinics are already overflowing with patients?

Dr. Jacoby. I would submit, from my personal viewpoint, Senator, that the combination of both techniques is the ideal. And this is what we have encouraged in the field for two reasons: One, it does have an opportunity to monitor a patient without having them come to the outpatient clinic.

Senator Stone. Is it cheaper that way?

Dr. Jacoby. It would, more than likely, be cheaper. However, I think some of the figures that were submitted to you in regard to the saving in beneficiary travel I would also have to question because, many times, the patient has to come to the hospital, at any rate, to be evaluated. As I say, it is the evaluation of the total patient, not just the pacemaker.

So, all those dollar savings that were submitted previously may be questioned because of that aspect.

Senator Stone. Well, without getting into the exact dollar amount, is it cheaper to have a telephonic report which shows that there is no immediate apparent need for a clinical visit than it is for a clinical visit which shows that there was no need for the clinical visit?

Dr. Jacoby. I would only answer that by saying that there is a requirement for the clinical visit. If, indeed, in the interim, particularly with our lithium-battery pacemakers we can use telephonic monitoring, and that would be a cheaper method of doing it.

Senator Stone. That is why you like the combination?

Dr. Jacoby. Absolutely, sir.

Senator Stone. Well, it seems logical to me, and I'm a layman, that if you can get frequent telephonic reports which read negative, that there is no real problem, and it cuts down on the psychological drive that people frequently have to go in and check, at cost to both themselves and the outpatient clinic. Does that make logic?

Dr. Jacoby. It is one of the advantages of telephonic monitoring, Senator. I agree.

Senator Stone. Is it cheaper for the VA to accomplish its own functioning central registry or to bid it out? In other words, is it cheaper to do this, in-house or by outside bidding with contractors?

Dr. Jacoby. It would be our impression, Senator, that this is cheaper in-house as part of our total patient monitoring system. However, the exact costs of this have not been determined.

Some of our data collecting, I believe, in comparing private corporations with the VA system, which we started to do, as you know, several years back, I think will probably answer part of that question.

Senator Stone. You sent out a circular in November requiring strict adherence to a request for the total number of cardiac patients at medical centers.

Did all the medical centers comply with that directive?

Dr. Jacoby. Senator, I can't answer that. If I may, I would like to ask Dr. Castellot, who is sitting in the audience. He could probably reply to that.

Dr. Castellot. Yes. All the medical districts which have the requirements in their cardiac pacemaker prostheses referral center plan have responded.

Senator Stone. I thank you, doctor.

In studying the Inspector General's report with which we began our hearing today and which has been out for some time, what steps has the VA taken to implement the report's recommendations, for example, to approve purchasing procedures and institute competitive bid practices?

Dr. Jacoby. Senator, if I may, I think that falls within Mr. Cook's area, and I would like him to respond.

Senator Stone. Mr. Cook?

Mr. Cook. Senator, we are discussing with several of the manufacturers now how we might proceed with a central contract.

We certainly do not intend to proceed with a central contract by a single model that everybody is going to use throughout the country.

Senator Stone. But you are trying to set up guidelines so that you can establish standards or parameters which would allow you to do competitive bidding?

Mr. Cook. Yes, sir. The issue is a little complex because you have heard the testimony as to how many models and so forth you have to deal with. We probably have to reduce it to a manageable size of those that are regularly used, and some of them may still remain outside a central contract if it is frequently used.

Senator Stone. Do you intend to consult the same type of medical experts that we had here this morning in the panel like Dr. Morris and Dr. Parsonnet, people like that, before you finalize such parameters for bidding?

Mr. Cook. Yes, sir. First of all, we have referred this to the VA's own committee dealing with these issues. They, in turn, would consult with the outside professional experts and in addition would consult with, and have been consulting with, FDA.

Senator Stone. What about the Inspector General's recommendation to define the employees who are responsible for ordering pacemakers? What has been done about that?

Mr. Cook. That has been done. That should have been, from the outset, members of my organization. It was not always.

Senator Stone. But now you have it that way?

Mr. Cook. Yes, sir.

Senator Stone. What about the IG's recommendation that the VA institute acceptable inventory controls?

Mr. Cook. That, too, I believe, was in a couple of the issues that have been referred to earlier that will be subject to a detailed inventory control.

Dr. Jacoby. May I clarify a little bit, Senator, what part of the problem was? In some of our medical centers, there were pacemakers present in our cardiology clinics that the VA did not own. The manufacturer had put them there against probable use.

Senator Stone. Is it possible that some of those on the shelf that had expired were of that sample, as opposed to your own purchased stock?

Dr. Jacoby. Yes, sir.

Senator Stone. Are you sorting that out now?

Mr. Cook. We have instructed medical centers that there will be no more manufacturers' owned products on the shelf. The VA will either buy it or we won't use it.

Senator Stone. When do you think you will be able to finish that inventory control system so that, if the IG went back, he would say you had now——

Mr. Cook. Part of it has been completed, and the remainder should be completed by within the next 2 months.

Senator Stone. What about the IG's recommendation that we reduce the VA's loss of Federal money due to failure to seek credit for pacemakers returned to manufacturers?

Mr. Cook. We issued an instruction about a month ago which said that all pacemakers would be returned to the manufacturers only through my organization so that we could seek credit.

It was not going through my organization, in many cases, and we didn't know it so we could not seek credit.

Senator Stone. Are you going to seek it now?

Dr. Jacoby. Yes, sir.

Senator Stone. Good, because we are under very great budget-curtailing pressures right now, and we need every dime we can recapture.

What about the IG's recommendation that the VA provide consistent pacemaker monitoring systems among the various VA medical centers?

Dr. Jacoby. Senator, I believe, again, this comes down to a clinical question, and the clinical question is how frequently should a patient be monitored.

The answer to that question is as often as the physician determines.

Senator Stone. But what about the purely mechanical life of the battery and things like that? Should that be subject to the physician's varying prescription or should there be at least a minimum monitoring?

Dr. Jacoby. As you heard, the Inter Society Commission for Heart Diseases Resources has made recommendations. You also heard this morning that the Federal health care financing—I only have to stress that they were not talking about a recommendation from a clinical standpoint; they were talking about a recommendation as to what would be paid for by medicare and other Federal assistance. So, I would submit, Senator, that this is a maximum.

In my judgment, the responsible thing to do would be to allow the clinicians who have acceptable guidelines within the field, and based on the type of patients that they have, to set up a monitoring system for each of their patients depending upon the type of pacemaker they have, the clinical condition of the patient, the longevity—that is, the time that that pacemaker has been implanted and, subsequently, any difficulty the patient was having with that pacemaker either at implantation or at the time of some mechanical failure.

If I may, Senator, I would like Dr. Fletcher, who is a practicing cardiologist, to comment on that question.

Senator STONE. Before he comments, I would like him to comment not only on that question, but on this impression.

I have just been sitting here for several hours, and my staff has been working and I have been working for more than a year on this.

And I am troubled by leaving it to any individual clinician not to allow monitoring because of the possibility of injury or damage to the unit during implantation.

Assuming that everything works beautifully before you put it in, maybe something went wrong putting it in. And if the VA's policy is to permit the individual, a clinician, to allow no monitoring as opposed to some, whatever the clinician thinks is appropriate, then don't we have a problem if we don't require at least some monitoring?

Dr. JACOBY. Senator, if an individual does not followup on following the implantation of a cardiac pacemaker, that individual is not following the standards of practice in the United States.

Now, that does without saying, without writing that down. We have a policy, and our policy clearly states that there will be followup surveillance of patients with cardiac pacemakers.

What we don't say is that you will do it every week, 2 weeks, 5 weeks, 6 months and so forth.

Senator STONE. You don't say that there must be at least some telephonic monitoring?

Dr. JACOBY. No, sir, we don't say that either because that may not be a requirement in that individual. I think the clinician, then, can make a determination as to how to follow that particular patient based on the individual, the patient as a whole, not as a device.

Senator STONE. I would like to hear from our cardiologist. Thank you.

Dr. FLETCHER. Thank you. I am at the Washington Hospital here, and have a specific interest in pacemakers. I have been involved in the field and give many discussions and lectures, one of which will be tomorrow. And I have a lot of data to provide that conference, obviously, from the hearing here which has been very illuminating along many lines.

Dr. Parsonnet, I think, stated things very clearly, and that is that the worst case patient is whom, I think, most of us are worried about and concerned about. And if you take 100 patients with pacemakers, you will find a segment of that population who is nowhere near a worst case.

The patients, he said, would have something like a 10 or 15 percent rate of dizzy spells if their pacemaker failed, and you would lose somewhere less than 2 percent of such patients.

We are out to correct that problem and make sure that all patients survive and have, at our own hospital, setup an in-house telephonic surveillance system for many years, about 5 or 6 years which, I might add, were told would no longer use. And this has caused us a little bit of personal trouble.

Senator STONE. Why can't you use it?

Dr. FLETCHER. We are told that there is an agreement with the company that makes it such that contract requirement don't allow personal followup by telephone if it excludes that company. And this is a problem we're having.

Obviously, we are working all these things out. I get a call something like two times a week from various doctors all over the country wondering what to do and how to do it.

Senator STONE. Doctor, what about this problem of possible damage to the unit during implantation so that, within a short period of time, there might be a failure.

Dr. FLETCHER. I think that is a very clear perception, and that is that, to the first 6 months of a unit's implantation, surveillance of some sort should take place.

Senator STONE. Now, what if there is no requirement for minimum surveillance during the first 6 months? You are leaving it to the clinician to decide not to.

Dr. FLETCHER. The clinician in the VA system, just like the clinician in the private sector, is responsible to that patient and, if he——

Senator STONE. Well, isn't the VA responsible, too?

Dr. FLETCHER. Oh, yes. But if he is responsible to that patient and the patient does run into problems, he is as liable to legal action as anybody else.

And, in general, he does the right thing in that setting. He does——

Senator STONE. Well, how about when he doesn't and if there is no minimum requirement for monitoring during that first 6 months, maybe even a week later, one of those patients is walking around with a dead battery or with a damaged terminal. I think that was the vulnerable area described—the connector to the lead, I think.

Dr. FLETCHER. I think, probably, throughout the country, there probably should be some policies. And I think it has been stated already that the VA has been in a leadership role there, first, in the initial implantation because I think, probably, at this point, it may well have to take that same role in the monitoring situation.

Senator STONE. I don't want to operate on my own appendix or on anything as a doctor, which I am not. And I don't want to substitute legislative wisdom or Government wisdom for medical wisdom. This is a medical issue.

But I have heard some logic and some basic minimum facts here today in which almost everyone seems to agree which is that, at least for the monitoring of the mechanical function of these units, telephonic is cheaper and it can help.

If that is the case, there can be injury or damage to the unit particularly early, which could be discovered by telephonic monitoring regardless of the intervals of clinical visit time being set by the clinician.

And, yet, it is the policy of the VA to leave the existence of even minimum telephonic monitoring to the discretion of the VA clinician.

While at the same time, everybody here today says that a combination of some kind is the ideal way to handle it.

Now, my preliminary thinking is—that there ought to be at least a minimum requirement by the VA for a monitoring combination after implantation.

Doesn't it make sense, leaving the latitude of parameters totally open to the clinician, to develop some minimum requirements for either telephonic or other monitoring to find out whether there is a problem?

Does that make any sense?

Dr. **Fletcher**. Yes, it makes sense. And, as you can see, we have followed the logic of that in our own practice and I know a lot of other doctors have followed the logic of that in their own practice.

And I would have to agree with you that there are probably some centers that may not be as up to date. And I think to get all centers in the country up to date in a short period of time to a minimum is a wise goal.

Senator **Stone**. Let me say that one of the great things that I have found in serving on this Committee is that we have been working with the VA health-care system, which is clearly an advance in so many areas medically because you have a large universe of data and you follow it as a national system.

There is no other medical system that I know of that works that effectively because of the capacity that you have.

So, when we have a capacity to do better, as we clearly can do, than anyone else in the pacemaker sphere, I would like to see the VA move in that direction, particularly if we can even save some money doing it.

Dr. Jacoby, do you or any of your panel have anything you would like to add to what we have covered?

Dr. **Jacoby**. Senator, I don't, except to certainly thank you for your interest in this program and for the interest in the Veterans' Administration and the veterans.

It is our desire, like yours, to see that the finest quality care is provided to the veterans, and we are going to pursue our efforts in the cardiac pacemaker field, as well as all others. Thank you.

Senator **Stone**. Well, I thank you all for participating. The Committee will be pursuing this in the next few months.

Again, thank you on behalf of all the veterans.

The hearing is adjourned.

[Whereupon, at 12:35 p.m., the hearing was adjourned, subject to the call of the Chair.]

[The prepared statement of Dr. Jacoby, Deputy Chief Medical Director, Veterans' Administration, and the response to written question submitted by Hon. Alan Cranston, Chairman of the Senate Committee on Veterans' Affairs, follow:]

PREPARED
STATEMENT OF

W. J. JACOBY, JR., M.D.
DEPUTY CHIEF MEDICAL DIRECTOR

DEPARTMENT OF MEDICINE AND SURGERY
THE VETERANS ADMINISTRATION

ON

VETERANS ADMINISTRATION CARDIAC PACEMAKER POLICY

BEFORE THE

SENATE VETERANS AFFAIRS COMMITTEE

APRIL 23, 1980

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

IT IS MY PLEASURE TO BE HERE TODAY TO PROVIDE AN OVERVIEW AND ANALYSIS OF THE VETERANS ADMINISTRATION'S CARDIAC PACEMAKER PROGRAM. WE WILL ATTEMPT IN OUR TESTIMONY TO RESPOND TO THE IMPORTANT QUESTIONS YOU HAVE RAISED IN YOUR OVERSIGHT OF THIS PROGRAM. AS WE REVIEW THE HISTORICAL PERSPECTIVES, THE CURRENT STATUS, AND THE VA'S FUTURE PLANS WITH REGARD TO OUR POLICIES FOR PROVIDING QUALITY CARE TO THOSE PATIENTS REQUIRING CARDIAC PACEMAKERS, WE SHOULD BEAR IN MIND THAT THE VA IS A LEADER IN THIS AREA AND IS THE ONLY HEALTH CARE SYSTEM WITHIN THE UNITED STATES THAT HAS ADDRESSED A CARDIAC PACEMAKER PROGRAM ON A NATIONAL BASIS. IT HAS DEVELOPED SOME UNIQUE AND COMPREHENSIVE APPROACHES TO RESOLVING MANY OF THE MAJOR PROBLEMS THAT ARE ASSOCIATED WITH THIS ISSUE. SOME PROBLEMS REMAIN, BUT EACH IS BEING ADDRESSED BY VA CENTRAL AND FIELD ADMINISTRATION IN A COMPREHENSIVE AND RESPONSIBLE FASHION. WE TRUST THAT THIS TESTIMONY AND SUPPORTING DOCUMENTATION WILL LEAD TO A MORE COMPLETE UNDERSTANDING OF THE VA'S ROLE AND ACTIONS IN THIS REGARD.

SURVEILLANCE OF PACEMAKER RECIPIENTS IS NECESSARY IN ORDER TO PROVIDE PROPER MEDICAL CARE. SINCE CARDIAC PACEMAKERS ARE MECHANICAL DEVICES IMPLEMENTED IN PATIENTS WITH SIGNIFICANT ORGANIC DISEASE, THERE ARE NUMEROUS POTENTIAL OPPORTUNITIES FOR ADVERSE EFFECTS. THERE IS A PREDICTABLE RISK OF FAILURE OF SOME PART OF THE PACING SYSTEM, OF DEVELOPMENT OF INFECTION AND OF PROGRESSION OR DEVELOPMENT OF HEART DISEASE OR ARRHYTHMIAS WHICH CAN INTERFERE WITH THE PERFORMANCE OF THE PACEMAKER. PROSTHESIS MALFUNCTION WILL RESULT FROM BATTERY DEPLETION, IF ELECTRONIC CIRCUITRY FAILS, IF PULSE GENERATOR LEADS BECOME DISCONNECTED, IF LEADS ARE INTERRUPTED OR THEIR INSULATION IS DEFECTIVE, AND IF ELECTRODES ARE DISPLACED FROM THE SURFACE OF A HEART. A PATIENT'S HEART DISEASE

MAY PROGRESS BEYOND THE POINT IN WHICH A PROSTHESIS IS DESIGNED TO BE EFFECTIVE. ALTHOUGH, THE PROSTHESIS WOULD NOT NECESSARILY BE INVOLVED IN THE PROGRESSION OF THE DISEASE, PACEMAKER SURVEILLANCE MAY ASSIST IN THE EARLY DETECTION OF CARDIAC DETERIORATION.

PACING DEVICES HAVE SEVERAL LIMITATIONS, ONE OF WHICH IS THE ELECTRICAL SOURCE EMPLOYED. MERCURY-ZINC BATTERIES HAVE BEEN USED AND THEY HAVE A CALCULATED LIFE OF ABOUT TWENTY-FOUR MONTHS. ABOUT THREE YEARS AGO LITHIUM ALLOY BATTERIES BECAME AVAILABLE. THESE THEORETICALLY HAVE CALCULATED SURVIVAL RATES RANGING FROM FIVE TO FIFTEEN YEARS. IN ACTUAL PRACTICE IT HAS BEEN NOTICED THAT A SMALL PROPORTION OF THESE BATTERIES BECOME DEFECTIVE WITHIN TWO TO THREE YEARS.

HUMAN MISTAKES CAN ALSO OCCUR IN THE MANUFACTURE AND INTEGRATION OF PACEMAKER COMPONENTS, SUCH AS MICROPROCESSOR CHIPS, WIRES, DIODES AND RESISTORS. THESE WILL OCCUR IN SPITE OF CAREFUL DESIGN AND TESTING PROCEDURES.

NEW TECHNOLOGIES WILL CONTINUE TO HAVE A SIGNIFICANT IMPACT ON PACEMAKING DEVICES AND SURVEILLANCE. THE DEVELOPMENT OF NEW POWER SOURCES, SUCH AS THE NUCLEAR BATTERY, WILL INCREASE THE USEFUL LIFE OF SUCH DEVICES. THE DEVELOPMENT OF DIFFERENT TYPES OF PACEMAKERS WILL CONTINUE AS THE PROFESSION HAS EXPERIENCED WITH FIXED RATE AND DEMAND DEVICES. WE CAN ANTICIPATE PROGRESSIVE DEVELOPMENTS IN INSULATION, LEADS, METALS TECHNOLOGY AND IN OTHER AREAS THAT WILL IMPROVE CARDIAC PACEMAKER FUNCTION.

THE ADVANTAGES OF TELEPHONIC CARDIAC PACEMAKER MONITORING INCLUDE EARLY DETECTION OF MINOR BUT SIGNIFICANT CHANGES IN PACEMAKER FUNCTIONING, SPEED OF PERFORMANCE, CONVENIENCE TO PATIENTS, REASSURANCE OF PATIENTS, COST AND ENERGY SAVINGS VIA REDUCED TRAVEL, EASE OF COMPUTERIZATION OF DATA (TO ASSIST PATIENT FOLLOW-UP AND DETECTION OF DEFECT TRENDS), AND POTENTIAL RESEARCH APPLICATIONS. DISADVANTAGES OF TELEPHONIC CARDIAC PACEMAKER MONITORING INCLUDE THE LIMITED TYPE OF EVALUATION THAT IS POSSIBLE OVER THE TELEPHONE AS OPPOSED TO THAT WHICH IS POSSIBLE DURING A CLINIC VISIT, THE NEED FOR A QUALIFIED PERSON TO INTERPRET THE DATA, THE USE OF MECHANICAL EQUIPMENT WHICH MIGHT FAIL, AND THE DIFFICULTIES IN KEEPING ABREAST IN A RAPIDLY EVOLVING TECHNICAL FIELD. ACCORDING TO INFORMATION PROVIDED BY VA PROFESSIONAL STAFF AND THE VA MARKETING CENTER AT HINES, ILLINOIS, THE SCOPE OF PACEMAKER MONITORING SERVICES AVAILABLE FROM PRIVATE FIRMS VARIES WIDELY. THERE ARE QUESTIONS REGARDING THE ABILITY OF SOME PRIVATE

COMPANIES TO PROVIDE THE NECESSARY COORDINATION OF A CENTRAL PATIENT AND PACEMAKER REGISTRY THAT WOULD INCLUDE DATA DERIVED FROM TELEPHONIC TRANSMISSION AND CLINICAL EVALUATION. HOWEVER, THIS ISSUE IS FAR FROM DECIDED AND THE EVOLUTION OF THE VA REGISTRY SYSTEM AND SUBSEQUENT COMPARISONS WITH THOSE AVAILABLE IN THE PRIVATE SECTOR WILL PROVIDE US WITH MORE SPECIFIC INFORMATION IN THE FUTURE. DEVELOPMENT OF A COMPUTERIZED TELEPHONIC MONITORING SYSTEM OR SYSTEMS WITHIN THE VETERANS ADMINISTRATION MAY OFFER CERTAIN POTENTIAL ADVANTAGES COMPARED TO USE OF PRIVATE CONTRACTORS. VA PROFESSIONAL STAFF WOULD BE DIRECTLY INVOLVED AND THE DATA COMPILED MAY BE MORE READILY CORRELATED WITH THE PATIENT'S OVERALL CLINICAL CARE. THE SYSTEM MIGHT ALSO BE MORE RESPONSIVE TO THE INVESTIGATIONAL AND TRAINING NEEDS OF VA STAFF. IN ADDITION, AN "IN-HOUSE" SYSTEM MIGHT BE MORE COST-EFFECTIVE AND THIS WILL BE ADDRESSED BELOW.

THE FIRST CARDIAC PACEMAKER WAS IMPLANTED IN A PATIENT IN 1958. SINCE THAT TIME, THE VETERANS ADMINISTRATION HAS PARTICIPATED IN THE DEVELOPMENT AND USE OF CARDIAC PACEMAKERS IN THE UNITED STATES. SOME VA PHYSICIANS WERE INVOLVED IN THE EARLY PIONEER IMPLANTATION ACTIVITIES AND HAVE COLLABORATED WITH OTHER SCIENTISTS WHO HAVE EXPLORED, AND ARE STILL EXPLORING NEW TECHNOLOGIES IN THIS FIELD. AS A POINT OF FACT, THE FIRST NUCLEAR-POWERED CARDIAC PACEMAKER IMPLANTED IN THE UNITED STATES WAS ACCOMPLISHED AT THE VA MEDICAL CENTER, BUFFALO, IN THE EARLY 1960'S.

THE VA'S ORIGINAL PACEMAKER IMPLANTATION PROGRAM GREW SLOWLY. ROUTINE FOLLOW-UP PROCEDURES FOCUSED PRIMARILY ON THE CARE OF THE SURGICAL INCISION, THE POSSIBILITY OF INFECTIONS, HEMORRHAGES, DISLOGEMENT OF THE LEADS, ETC. AT THAT TIME, PACEMAKER BATTERIES WERE NOT DEPENDABLE AND REPLACEMENT OF A PACEMAKER AFTER SIX TO TWELVE MONTHS WAS COMMON. THE NUMBER OF MANUFACTURERS AND THE VARIETY OF PACEMAKERS PRODUCED WAS LIMITED. DURING THIS TIME THE INTER-SOCIETY COMMISSION FOR HEART DISEASE RESOURCES WAS ESTABLISHED AND DEVELOPED STATE-OF-THE-ART GUIDELINES IN THE FIELD OF CARDIAC PACEMAKER NOMENCLATURE, IMPLANTATION AND FOLLOW-UP. ALONG WITH THEIR COLLEAGUES IN THE COMMUNITIES AND THE UNIVERSITIES, VA PHYSICIANS HAVE GENERALLY FOLLOWED THESE GUIDELINES.

THE PROGRAM EVOLVED WITH THE DEVELOPMENT OF NEW LEADS, PROGRAMMABLE PACEMAKERS, AND EXTENDED LIFE BATTERIES. PULSE GENERATORS LASTED LONGER AND PACEMAKER MODELS AND VENDORS MULTIPLIED. DEFICIENT PACEMAKERS GRADUALLY DISAPPEARED FROM THE MARKET, AND FOREIGN VENDORS AND PRODUCTS APPEARED ON THE SCENE. THESE CHANGES ALSO BROUGHT DIVERSIFICATION OF THE MEDICAL PERSONNEL WHO BECAME INVOLVED

WITH PACEMAKER MANAGEMENT.

AS THE NUMBER AND COMPLEXITY OF PACEMAKERS INCREASED AND WITH THE INCREASING NUMBER OF VA PATIENTS BECOMING PACEMAKER RECIPIENTS, THE VA FELT THE NEED TO DEVELOP SYSTEM-WIDE POLICIES IN THIS AREA. THE FIRST STEP IN THE DEVELOPMENT OF OUR POLICY WAS THE CREATION IN 1975 OF A VA CENTRAL OFFICE PACEMAKER COMMITTEE TO ASSIST IN THE MANAGEMENT OF THIS PROGRAM. THIS COMMITTEE, COMPOSED OF PHYSICIANS, BIOMEDICAL ENGINEERS AND STAFF ADMINISTRATORS, WAS CHARGED WITH KEEPING ABREAST OF DEVELOPMENTS IN THIS FIELD, WITH COLLECTING DATA ON VA PACEMAKER ACTIVITIES, WITH ESTABLISHING A PACEMAKER REGISTRY TO IDENTIFY AND MONITOR THE TOTAL VA CARDIAC PACEMAKER POPULATION, AND WITH DEVELOPING A FORMAL COMPREHENSIVE VA POLICY ENCOMPASSING THE MANY VARIABLES IN THE CARDIAC PACEMAKER FIELD. THESE ACTIVITIES HAVE NOW BEEN ACCOMPLISHED AND ARE DESCRIBED IN GREATER DETAIL BELOW.

THE VA'S OVERALL POSITION ON CARDIAC PACEMAKER PROSTHESES IS ESTABLISHED IN DM&S CIRCULAR 10-79-269. THIS CIRCULAR ADDRESSES IMPLANTATION IN VETERANS WHO REQUIRE SUCH DEVICES, FOLLOW-UP OF THESE VETERANS, COLLECTION OF DATA ABOUT CARDIAC PACEMAKERS, AND THE ESTABLISHMENT OF CARDIAC PACEMAKER PROSTHESES REFERRAL CENTERS (CPPR CENTERS). EACH OF THE VA'S 28 MEDICAL DISTRICTS HAS BEEN ASKED TO DESIGNATE ONE OR MORE VA MEDICAL CENTERS WITHIN ITS AREA OF JURISDICTION AS A CPPR CENTER(S). IT IS OUR POLICY THAT PERMANENT CARDIAC PACEMAKER PROSTHESES WILL BE IMPLANTED AND REPLACED ONLY IN THE CPPR CENTER(S). VA CENTRAL OFFICE HAS REVIEWED 28 DISTRICT-WIDE PLANS FOR PACEMAKER IMPLANTATION AND REPLACEMENT. THESE PLANS WILL NOT BE STATIC BUT WILL BE SUBJECT TO PERIODIC REVIEW AND REVISION, AS NECESSARY.

THE CIRCULAR REAFFIRMS OUR COMMITMENT TO PROVIDE ELIGIBLE VETERANS WHO HAVE CARDIAC DISEASES REQUIRING CARDIAC PACEMAKERS WITH PROSTHESES OF THE HIGHEST QUALITY AND REQUIRES THAT ADMINISTRATIVE REVIEWS AND PROFESSIONAL SUPERVISION OF SUCH PATIENTS WILL BE ACCOMPLISHED AND DOCUMENTED. THIS CIRCULAR AND OTHER VA DIRECTIVES REFLECT NOT SO MUCH A MODIFICATION OF VA POLICY, BUT A REAFFIRMATION, AS MENTIONED PREVIOUSLY, OF AN ACCEPTABLE MEDICAL PRACTICE THAT HAS EXISTED IN OUR MEDICAL CENTERS. WE HAVE EMPHASIZED THE CORRECTION OF EXISTING DEFICIENCIES AND HAVE ESTABLISHED POLICIES TO IMPROVE CONTROL AND COORDINATION THROUGHOUT THE VETERANS ADMINISTRATION.

AS A COMPONENT OF THIS REGIONALIZED APPROACH TO HEALTH CARE DELIVERY, EACH CPPR HAS DEVELOPED OR IS DEVELOPING, A FOLLOW-UP SURVEILLANCE PLAN TO INSURE APPROPRIATE CONTINUING CARE. FOLLOW-UP SURVEILLANCE OR MONITORING CAN BE ACCOMPLISHED IN ONE OF THREE WAYS: (1) BY DIRECT CLINICAL SURVEILLANCE (EVALUATION) OF A PATIENT, (2) BY REMOTE TELEPHONIC SURVEILLANCE, OR (3) BY COMBINATION OF BOTH OF THESE METHODS. THE METHODS AND SCHEDULES TO BE USED ARE DETERMINED BY THE ATTENDING PHYSICIAN AND ARE BASED ON MANY FACTORS, THE PRIMARY ONE BEING THE PATIENT'S CLINICAL STATUS AND CARDIOVASCULAR REQUIREMENTS.

SINCE TELEPHONIC MONITORING HAS ASSUMED SUCH IMPORTANCE IN THE FOLLOW-UP CARE OF PACEMAKER RECIPIENTS, WE HAVE BEEN EXTREMELY INTERESTED IN EXPLORING THE FULL CAPABILITIES OF OUR EXISTING IN-HOUSE AND PRIVATE SECTOR SYSTEMS. VA MEDICAL CENTER, SAN FRANCISCO, FOR EXAMPLE, BEGAN A VA CENTRAL OFFICE SPONSORED IN-HOUSE SURVEILLANCE ACTIVITY IN 1976 AND HAS A COMPREHENSIVE PROGRAM IN OPERATION IN MEDICAL DISTRICT #27.

INSOFAR AS PRIVATE SECTOR TELEPHONIC CARDIAC PACEMAKER MONITORING CAPABILITIES ARE CONCERNED, THE VA MARKETING CENTER, HINES, ILINOIS, HAS THUS FAR TESTED THE CARDIAC PACEMAKER SERVICES OF FIVE PRIVATE SECTOR COMPANIES. THE FIRST OF THESE TO GAIN APPROVAL WAS PACEMAKER DIAGNOSTIC CLINIC OF AMERICA, GAINESVILLE, FLORIDA. THIS COMPANY WAS AWARDED A VA DECENTRALIZED CONTRACT. WE HAVE NOW APPROVED FOR FUTURE CONTRACTS THREE ADDITIONAL COMPANIES THAT ARE CAPABLE OF PROVIDING ACCEPTABLE CARDIAC PACEMAKER PROSTHESES MONITORING SERVICES.

THE DECENTRALIZED CONTRACT NEGOTIATED WITH PDC WAS AWARDED IN MAY 1979. EFFECTIVE DATES OF THIS AGREEMENT ARE JULY 1, 1979 to JUNE 30, 1980. THIS CONTRACT AND OTHER RELEVANT DOCUMENTS ARE BEING SUBMITTED AS PART OF THE RECORD. IT SHOULD BE NOTED THAT THE CONTRACT DOES NOT CONTAIN AN AGREEMENT THAT MONITORING SERVICES FOR A SPECIFIC NUMBER OF PATIENTS WOULD BE PURCHASED. MEDICAL CENTERS WERE TO PLACE ORDERS DIRECTLY WITH PDC FOR THEIR REQUIREMENTS AND THE VA MEDICAL CENTERS WOULD BE BILLED DIRECTLY FOR THE SERVICES PERFORMED BY THE COMPANY. THE CONTRACT ALSO ALLOWS THE VA TO MAKE MULTIPLE AWARDS TO OTHER ACCEPTABLE VENDORS FOR MONITORING SERVICES. IT WAS NOT THE INTENT OF THIS CONTRACT TO PRESENT A UNIFORM PACEMAKER MONITORING SYSTEM TO BE PROVIDED BY ONE CONTRACTOR BUT RATHER TO PROVIDE AN ACCEPTABLE MONITORING PROGRAM, AT A REASONABLE COST, TO OUR MEDICAL CENTERS. WITH THE AWARDING OF THE DECENTRALIZED CONTRACT TO PDC, THERE WAS SOME CONFUSION ON THE PART OF MANY OF THE CONCERNED PARTIES.

IN AN EFFORT TO RESOLVE ANY MISUNDERSTANDINGS, VA CENTRAL OFFICE HAS CONDUCTED A SERIES OF COMMUNICATIONS WITH ITS MEDICAL CENTERS, THE CONTRACTOR, CONGRESSIONAL OFFICES AND OTHER GROUPS INTERESTED IN THE CARDIAC PACEMAKER FIELD. ADDITIONAL VA CENTRAL OFFICE DIRECTIVES HAVE BEEN DEVELOPED AND ISSUED AND ARE BEING MADE A PART OF THE RECORD. THESE DIRECTIVES, COUPLED WITH A RESPONSIBLE APPROACH BY THE CONTRACTOR, HAVE SERVED TO RESOLVE MUCH OF THE CONFUSION AND TO FURTHER THE DEVELOPMENT OF THE VA'S CARDIAC PACEMAKER PROSTHESES PROGRAM.

FREE PACEMAKER MONITORING IS ALSO OFFERED BY SEVERAL PACEMAKER MANUFACTURERS AND SOME OF OUR MEDICAL CENTERS HAVE UTILIZED SUCH SERVICES. QUESTIONS HAVE BEEN RAISED ABOUT THE PROPRIETY OF USING THESE SERVICES AND IT HAS COME TO OUR ATTENTION THAT QUESTIONABLE BILLINGS MAY HAVE BEEN MADE UNDER THE MEDICARE PROGRAM FOR MONITORING FURNISHED TO VETERAN PATIENTS. WE HAVE INITIATED CONTACT WITH THE HEALTH CARE FINANCE ADMINISTRATION TO RESOLVE THIS ISSUE AND WE ARE ESTABLISHING A POLICY THAT PRECLUDES THE USE OF SUCH FREE SERVICES BY ALL VA FACILITIES.

WE ARE INITIATING A STUDY TO COMPARE THE EFFICIENCY, COST EFFECTIVENESS AND QUALITY OF SOME OF OUR VA MEDICAL CENTER-BASED TELEPHONIC SURVEILLANCE PROGRAMS WITH SEVERAL OF THOSE AVAILABLE IN THE PRIVATE SECTOR. THE COMPLETION OF THIS STUDY SHOULD PRODUCE RESULTS WITH CLINICAL AS WELL AS ECONOMIC IMPORT TO THE VA.

AS PART OF THE POLICY ON CARDIAC PACEMAKER PROSTHESES, THE VA IMPLEMENTED PROCEDURES TO ESTABLISH AN AUTOMATED REGISTRY AT EACH MEDICAL CENTER WITH A CENTRAL REGISTRY IN VA CENTRAL REGISTRY IN VA CENTRAL OFFICE. THIS REGISTRY WAS INITIATED IN NOVEMBER 1979, AND HAS BEEN FURTHER DEFINED IN SUBSEQUENT ISSUANCES. THE PURPOSE OF THIS REGISTRY IS TO PROVIDE A CONTINUOUS OVERVIEW OF SUCH PATIENTS, TO PROVIDE INFORMATION FOR IMPROVING THE QUALITY OF CARE RENDERED TO ALL PACEMAKER RECIPIENTS, AND TO DETERMINE POSSIBLE DEFECT TRENDS OCCURRING IN IMPLANTED CARDIAC PACEMAKERS. THE REGISTRY WILL ALSO PROVIDE A DATA BASE FOR FURTHER RESEARCH IN THE AREA OF PACEMAKER IMPLANTATION. THE TOTAL PACEMAKER POPULATION WAS DEFINED BY IDENTIFYING ALL PATIENTS WHO HAVE RECEIVED PERMANENT CARDIAC PACEMAKER PROSTHESES IN VA FACILITIES SINCE 1963, ALL PATIENTS WHO HAVE RECEIVED PERMANENT CARDIAC PACEMAKER PROSTHESES IMPLANTS IN NON-VA HOSPITALS UNDER VA AUSPICES SINCE 1963, AND ALL PATIENTS WHO RECEIVED SUCH PROSTHESES IN NON-VA HOSPITALS, NOT AT VA EXPENSE, BUT WHO HAVE BEEN AND/OR ARE CURRENTLY BEING FOLLOWED IN VA FACILITIES. THIS AUTOMATED DATA COLLECTION SYSTEM HAS BEEN DESIGNED TO PROVIDE THE FOLLOWING REPORTS. THE LIST IS NOT ALL INCLUSIVE AND THE VA WILL ASSESS THE NEED FOR FURTHER OUTPUTS AS THE SYSTEM IS DEVELOPED AND AS NEEDS ARE IDENTIFIED.

ACCESSION REPORT - INTENDED TO SHOW THE GROWTH OF THE PACEMAKER POPULATION ANNUALLY. THE REPORT WILL LIST PATIENTS PERMANENTLY IMPLANTED FOR THE FIRST TIME IN VA MEDICAL CENTERS AND THOSE IMPLANTED IN NON-VA HOSPITALS AT VA EXPENSE.

MANUFACTURERS REPORT - WILL LIST PATIENTS ACCORDING TO THE MANUFACTURER OF THE PULSE GENERATOR. THIS REPORT WILL FACILITATE PATIENT RECALL IF INFORMATION FROM THE FDA IS RECEIVED REGARDING DEFECTS IN SPECIFIC PACEMAKERS.

REPLACEMENT REPORT - WILL INDICATE THE NUMER OF PACEMAKERS AND PULSE GENERATORS WHICH REQUIRED REPLACEMENT DURING A REPORTING PERIOD. THIS REPORT IS ALSO DESIGNED TO PROVIDE AN INDEX TO THE LONGEVITY OF THE PULSE GENERATOR WHICH REQUIRED REPLACING. IT WILL THEN BE POSSIBLE TO ASSESS THE ACTUAL LIFE SPAN OF SELECTED PULSE GENERATORS AND COMPARE THESE RESULTS WITH THE LIFE EXPECTANCIES CLAIMED BY THE MANUFACTURER.

SURVIVAL REPORT - WILL INDICATE SURVIVING PACEMAKER RECIPIENTS BY THE NUMBER OF MONTHS SINCE EACH PATIENT HAD THEIR CARDIAC PACEMAKER IMPLANTED. THIS REPORT WOULD ALSO NOTE PATTERNS OF PACEMAKER LONGEVITY AND SERVE A USEFUL RESEARCH PURPOSE.

DEATH REPORT - WILL SHOW LOSSES FROM THE PACEMAKER PROGRAM AND SERVE AS AN INDEX FOR FURTHER RESEARCH IN THE AREA OF PACEMAKER FUNCTION.

MALFUNCTION REPORT - THIS WILL FACILITATE CLOSER FOLLOW-UP OF PATIENTS WITH PULSE GENERATORS THAT SHOW SIGNS OF IMPENDING FAILURE.

DATA SUBMITTED BY FIELD FACILITIES HAVE BEEN EDITED AND FORWARDED TO OUR ST. PAUL DATA PROCESSING CENTER. WE ANTICIPATE THAT KEY ENTERING WILL BE COMPLETED IN APPROXIMATELY FOUR TO FIVE WEEKS. THE FIRST MONTHLY PROCESSING OF THE DATA IS SCHEDULED TO BEGIN IN JULY 1980 WITH INSTALLATION OF THE ENTIRE SYSTEM IN SEPTEMBER 1980. SPECIFIC PROGRESS AND STATUS REPORTS AND OTHER DETAILED INFORMATION REGARDING THE CARDIAC PACEMAKER REGISTRY ARE BEING SUBMITTED AS PART OF THE RECORD.

ON FEBRUARY 13, 1980, THE OFFICE OF THE INSPECTOR GENERAL COMPLETED AN AUDIT OF THE PROCUREMENT AND MONITORING OF PACEMAKERS WITHIN THE VA. MAJOR FINDINGS AND RECOMMENDATIONS IN THIS AUDIT ADDRESSED THREE AREAS OF CONCERN -- PROCUREMENT, ACCOUNTABILITY AND RECALL OF CARDIAC PACEMAKERS. THE FOLLOWING ACTIONS HAVE BEEN OR WILL BE TAKEN BY THE VA RELATIVE TO THESE CONCERNS. THE VA

HAS HAD NO CENTRALIZED CONTRACT FOR THE PROCUREMENT OF PACEMAKERS AND RELATED ITEMS. PAST PROCUREMENT HAS BEEN BY MEANS OF INDIVIDUAL MEDICAL CENTER CONTRACTS AND BY USE OF A NON-MANDATORY FEDERAL SUPPLY SCHEDULE. IT HAS RECENTLY BEEN PROPOSED THAT CONTRACTING RESPONSIBILITY FOR ALL MEDICAL ITEMS (FSG 65) CURRENTLY ON FEDERAL SUPPLY SCHEDULES BE TRANSFERRED TO THE VA. IN THE MEANTIME, MANUFACTURERS OF PACEMAKERS (OR THEIR REPRESENTATIVES) KNOWN TO DO BUSINESS IN THE UNITED STATES HAVE BEEN CONTACTED IN ORDER TO DETERMINE THE EXTENT OF CURRENT SALES TO THE VA AND TO OBTAIN A SHOW OF INTEREST IN ENTERING INTO A POSSIBLE CENTRALIZED CONTRACT WITH THE VA FOR CARDIAC PACEMAKER PROSTHESES AND RELATED ITEMS. ALL MAJOR MANUFACTURERS CONTACTED ARE INTERESTED IN PURSUING SUCH A CONTRACT. SUCH ARRANGEMENTS COULD PROVE TO BE MORE COST EFFECTIVE, MORE RESPONSIVE TO VA NEEDS, AND WOULD ASSIST THE VA IN PROVIDING GREATER CONTROL OF ITS PACEMAKER PROGRAM. CONTRACT COORDINATION IS IN PROCESS.

IN THE AREA OF PACEMAKER ACCOUNTABILITY, THE VA IS PREPARING A CHANGE IN ITS REGULATIONS TO ADDRESS SPECIFICALLY THE RESPONSIBILITY OF THE DEPARTMENT OF MEDICINE AND SURGERY AS RELATED TO THE PROCUREMENT, RECEIPT, DELIVERY, INVENTORY AND DISPOSAL OF CARDIAC PACEMAKERS.

FOR MANY YEARS THE VA HAS UTILIZED THE FOOD AND DRUG ADMINISTRATION'S REGULAR RECALL NOTIFICATION PROCEDURES TO INFORM ALL OF ITS MEDICAL CENTERS ABOUT DEVICES IDENTIFIED AS BEING DEFECTIVE. THE FDA HAS ALSO SENT SUCH NOTICES DIRECTLY TO VA FACILITIES. IN EARLY 1975 THE VA SIGNED A MEMORANDUM OF UNDERSTANDING WITH THE FDA TO EXCHANGE MEDICAL DEVICE EXPERIENCE. THIS HAS BEEN UPDATED PERIODICALLY. A PREVIOUSLY EXISTING DIRECTIVE (DM&S CIRCULAR 10-79-134) ADDRESSED THE RECALL OF POTENTIALLY HAZARDOUS PRODUCTS AND A CHIEF MEDICAL DIRECTOR'S LETTER WAS PUBLISHED TO RE-EMPHASIZE THIS ISSUE AND TO REQUEST ALL VA MEDICAL CENTERS TO NOTIFY CENTRAL OFFICE UPON COMPLETION OF LOCAL WRITTEN RECALL PROCEDURES. ALL HAVE INDICATED COMPLETION OF THIS REQUIREMENT. IN JANUARY 1980, THE VA MARKETING CENTER BEGAN ISSUING A "MONTHLY RECALL SUMMARY." THIS PUBLICATION IS USED AS A CHECKLIST TO ASSURE THAT CORRECTIVE ACTION HAS BEEN TAKEN CONCERNING PREVIOUSLY ANNOUNCED RECALLS AND FIELD CORRECTIONS BY FDA AS WELL AS VA MARKETING CENTER SUSPENSIONS. WITH FULL IMPLEMENTATION OF THE ABOVE-NOTED ACTIONS, COMPLIANCE WITH RECOMMENDATIONS IN THIS AUDIT WILL BE ACCOMPLISHED. IT SHOULD BE NOTED THAT THE AUDIT BY THE INSPECTOR GENERAL RAISED A QUESTION CONCERNING THE REUTILIZATION OF CARDIAC PACEMAKER PROSTHESES EXPLANTED FROM RECENTLY DECEASED PATIENTS.

A DM&S CIRCULAR ISSUED FEBRUARY 13, 1980, PROHIBITS THIS PRACTICE. CURRENT POLICY STATES THAT EXPLANTED CARDIAC PACEMAKER PROSTHESES MAY BE USED FOR RESEARCH PURPOSES OR BE RETURNED TO SUPPLY SERVICE FOR FINAL DISPOSITION. WE BELIEVE THAT IMPLANTING RECYCLED PACEMAKERS WOULD HAVE A SIGNIFICANT NEGATIVE IMPACT ON PATIENT MORALE AND THE DOCTOR-PATIENT-FAMILY RELATIONSHIP. FURTHER, the FDA HAS QUESTIONED WHETHER PACEMAKERS CAN BE PROPERLY RESTERILIZED AND WHETHER PROBLEMS ARE POSED BECAUSE OF THE POTENTIAL FOR INTRODUCING FOREIGN PROTEIN MATTER IN THE RECIPIENT.

I WOULD BE LESS THAN CANDID IF I ATTEMPTED TO DOWNPLAY THE VA'S CONCERN ABOUT THE ENTIRE PACEMAKER MONITORING ISSUE. WE ARE WORKING WITHIN DEFINED POLICIES AND WITH ORGANIZATIONAL STRUCTURES AND INTERPERSONAL RELATIONSHIPS THAT MUST BE CONSIDERED WHEN THIS ISSUE IS DISCUSSED. HOWEVER, IT IS IMPORTANT TO NOTE THAT IN THIS FIELD, AS WITH MANY OTHER MEDICAL CARE ACTIVITIES, THERE IS A SUBTLE YET COMPLEX INTERRELATIONSHIP BETWEEN PROVIDING CENTRALIZED GUIDANCE TO FIELD FACILITIES AND ENCOURAGING APPROPRIATE LOCAL JUDGMENT. WE ARE STILL FACED WITH PERCEPTIONS ON THE PART OF MANY OF OUR MEDICAL CENTER PHYSICIANS THAT ATTEMPTS ARE BEING MADE TO DICTATE THE KIND OF HEALTH CARE THAT THEY SHOULD BE DELIVERING TO THEIR CARDIAC PATIENTS. THIS IS A SERIOUS MATTER BUT, I AM HAPPY TO SAY, PROGRESS HAS BEEN MADE IN ALLEVIATING MANY OF THESE CONCERNS BECAUSE OF MAJOR EFFORTS BY OUR MEDICAL AND ADMINISTRATIVE LEADERSHIP. I WOULD ANTICIPATE THAT WITH CONTINUED EXPERIENCE WITH EXISTING POLICIES AND WITH THE WIDER SELECTION OF AVAILABLE IN-HOUSE AND VENDOR MONITORING PROGRAMS, FURTHER CONCERNS IN THIS REGARD WILL BE RESOLVED.

IN SUMMARY, THE VA'S CARDIAC PACEMAKER PROGRAM IS OPERATING UNDER DEFINED POLICIES AND PROCEDURES AND IS EMPLOYING BOTH IN-HOUSE AND COMMERCIALLY AVAILABLE TECHNOLOGIES TO FURTHER THE GOAL OF PROVIDING THE BEST POSSIBLE PATIENT CARE TO CARDIAC PACEMAKER RECIPIENTS. THE VA IS THE FIRST MAJOR HEALTH CARE DELIVERY SYSTEM AND THE FIRST FEDERAL AGENCY TO TAKE SUCH COMPREHENSIVE ACTION.

THE PROGRAM WILL CONTINUE TO GROW IN A PURPOSEFUL MANNER, TO THE BENEFIT OF ALL VETERANS ELIGIBLE FOR CARDIAC PACEMAKER CARE. VA CARDIAC SPECIALISTS WILL STAY ABREAST OF THE STATE-OF-THE-ART IN THIS COMPLEX FIELD. CONTINUING

EDUCATION WILL OCCUR BY MEANS OF APPROPRIATE CENTRAL OFFICE INFORMATIONAL POLICY AND PROCEDURAL DIRECTIVES, BY EMPLOYING THE RESOURCES AVAILABLE AT OUR REGIONAL MEDICAL EDUCATION CENTERS, BY PARTICIPATION IN PROFESSIONAL MEETINGS, BY EXPANDED CONTACTS WITH OTHER FEDERAL AND PRIVATE SECTOR RESOURCES, AND BY WHATEVER MEANS ARE NECESSARY TO FURTHER THESE AIMS. THE DEVELOPMENT OF THE VA PACEMAKER REGISTRY WILL PROVIDE US WITH A VITAL TOOL FOR MORE COORDINATED AND COMPREHENSIVE MONITORING ACTIVITIES. MANY OF THE EARLY DEVELOPMENTAL PROBLEMS NO LONGER EXIST AND THOSE THAT REMAIN ARE RECOGNIZED AND ARE BEING PURSUED AGRESSIVELY. ALTHOUGH WE HAVE COME A LONG WAY IN THE CARDIAC PACEMAKER FIELD, AND NOW HAVE A FORMAL PROGRAM WHICH IS BALANCED, FLEXIBLE AND APPROPRIATE FOR OUR CENTRALIZED/DECENTRALIZED CONCEPT OF HEALTH CARE DELIVERY, WHAT REMAINS TO BE DONE WILL BE DONE.

MR. CHAIRMAN, THIS CONCLUDES MY FORMAL PRESENTATION. I WILL BE PLEASED TO RESPOND TO ANY QUESTIONS YOU MAY HAVE.

Response of the Veterans' Administration to Written Questions Submitted by Hon. Alan Cranston, Chairman of the Senate Committee on Veterans' Affairs

Question 1. How many VA Medical Centers currently operate in-house telephonic monitoring programs? How are such individual programs funded?

Answer 1. At the present time there are 42 VA medical centers with functioning in-house telephonic monitoring programs. These individual in-house programs are funded as part of the medical center's general operating patient care budget. There is no special program to fund such activities.

Question 2. Testimony received from expert witnesses—several cardiologists—on April 23, indicated that it would be unwise to promulgate guidelines to require that a specific schedule be maintained by attending physicians with respect to clinical and telephonic monitoring of VA pacemaker patients. On the other hand, those witnesses supported the establishment of a minimum requirement for the clinical or telephonic monitoring of patients with pacemaker implants. What balance of clinical and telephonic monitoring do you believe would represent a realistic minimum guideline for attending physicians in VA medical centers?

Answer 2. Although the concept of establishing minimum guidelines for the clinical and telephonic monitoring of cardiac pacemaker patients may have some appeal, there are practical difficulties in attempting to do so. Because of the clinical variability of individual patients, the technical complexity of various cardiac pacemakers and the continuing evolution of this parameter of cardiac care, the VA believes this decision is best left up to the professional judgment of the responsible physician and should be based on the individual patient's clinical requirements. This is in basic agreement with the philosophy contained in the guideline of the Inter-Society Commission for Heart Disease Resources and conforms with cardiac pacemaker care provided in the private sector.

Question 3A. With respect to the decentralized contract with PDC (Pacemaker Diagnostic Clinic of America), which was effective July 1, 1979, were all VA medical centers required, at that time, to contract for telephonic monitoring services from PDC as opposed to initiating in-house programs?

Question 3B. If so, is that still true today?

Answer 3A. If personnel at a medical center determined that they wanted to contract out, they had to use contractors on the schedule of the decentralized contract. It was not the intent of the subject contract to require all VA medical centers to obtain their requirements for telephonic monitoring from one source (PDC). The Contract was awarded and the decentralized schedule was issued to provide a source for this service to those VA medical centers desiring to establish a contract, but it did not interfere with those programs already in place. A subsequent determination by the VA General Counsel interpreted the contract as prohibiting the initiation of a new in-house program during the effective date of the PDC contract, if the contractual liability was to be avoided, but as allowing these in-house programs established prior to July 1, 1979, to continue to function.

Answer 3B. No. Under the new decentralized contract (effective July 1, 1980) there is no restriction on the establishment of in-house programs.

Question 3C. Were any in-house programs discontinued as a result of the PDC contract?

Answer 3C. Yes.

Question 3D. If so, why and what VA medical centers had in-house programs that were discontinued?

Answer 3D. The program started at Manhattan VAMC in November 1979, was stopped, since it had been initiated after July 1, 1979.

Question 4. In addition to PDC, what three companies have been approved for future contracts for telephonic monitoring services? Where are these companies located?

Answer 4. Under the current decentralized contract the following companies have been approved to provide telephone monitoring services:

Cardiac Datacorp Inc., 1280 Blue Hills Avenue, Bloomfield, Conn. 06002.
Cardiac Monitoring Inc., 321 Northlake Blvd., North Palm Beach, Fla. 33408.
Cardio-Pace Evaluation System, Inc., 9999 S.W. Wilshire Street, Portland, Oreg. 97225.
Medalert Corporation, Division of Survival Technology Inc., One Park Plaza, New York, N.Y. 10001.
Medicalelectrographic Sciences, 701 Welch Road, Suite 217, Stanford, Calif. 94305.
Pacemaker Diagnostic Clinic of America, Inc., 4020 W. Newberry Road, Suite 400, Gainesville, Fla. 32607.
Pacemaker Evaluation Service, 56 Haddon Avenue, P.O. Box 117, Haddonfield, N.J. 08033.

Question 5A. Were other VA medical districts informed of Medical District 27's very successful in-house pacemaker surveillance program, which the Deputy Chief Medical Director mentioned on page 5 of his submitted testimony?

Answer 5A. Through their physician members on VA Central Office's Cardiology Advisory and Cardiac Pacemaker Advisory Committees, many VA medical districts learned of Medical District 27's in-house pacemaker surveillance system. Other medical districts have become aware of it through informal contacts between physicians at professional meetings, via telephone, etc.

Question 5B. What kind of monitoring techniques does that program employ?

Answer 5B. Medical District 27's cardiac pacemaker surveillance program combines both appropriate clinical monitoring and state of the art telephonic monitoring. For telephonic monitoring cardiac pacemaker recipients are provided with transmitters by means of which they transmit ECG and pacemaker electronic signals to VAMC San Francisco according to individualized schedules. VAMC San Francisco is well supplied with analytical instrumentation and also uses one of the hospital's computers to help coordinate the entire program. Recently the hospital's capability to transmit and analyze ECG wave forms for the District has been upgraded through the acquisition of teletransmitting equipment.

Question 6A. On page 3 of the Deputy Chief Medical Director's submitted statement, he mentions the etablishment of the Inter-Society Commission for Heart Disease Resources.

When was it established?

Answer 6A. The Inter-Society Commission for Heart Disease Resources was established in 1966 pursuant to Section 907 of Public Law 89-239. The purpose of this Commission is to develop guidelines for optimal medical resources for the prevention and treatment of cardiovascular diseases. It was not the charge of this Commission to develop medical practice policy for physicians. Therefore, the guidelines of the Commission, to the extent that they are involved with medical practice, are only advisory in nature.

Question 6B. When did it first issue state-of-the-art guidelines with respect to pacemaker procurement, implantation, monitoring, and maintenance of pacemaker and patient registries?

Answer 6B. The earliest guidelines relating to cardiac pacemaker matters we are aware of were published in 1974.

Question 6C. How were individual VA medical centers informed of these state-of-the-art guidelines?

Answer 6C. Individual VA medical center physicians have learned of these state of the art guidelines in many ways, e.g. they are published in the medical journal circulation and may be commented on in other journals such as American Journal of Cardiology, American Heart Journal, Journal of Thoracic and Cardiovascular

Surgery, etc.; attendance and participation in discussions at professional meetings; contact with colleagues; and review of manufacturers' literature.

Question 6D (1). When did the Commission first consider telephonic monitoring as a mode of surveillance?

Answer 6D (1). The Commission first mentioned telephonic monitoring in 1974.

Question 6D (2). What guidelines, if any, were issued at that time?

Answer 6D (2). The Commission suggested that the program for each patient be individualized according to the needs of that patient.

Question 6D (3). Has the Commission's position on telephonic monitoring changed since that time?

Answer 6D (3). The Commission recently reviewed its 1974 guideline and made some minor changes.

Question 6D (4). If so, in what respect?

Answer 6D (4). The main change refers to the revised frequency of monitoring made necessary by the substitution of lithium-powered pulse generator batteries for the older zinc-mercury batteries.

Question 6E (1). When did the Commission first consider what benefits might or might not be gained through maintenance of pacemaker and patient registries?

Answer 6E (1). In their 1974 report the Commission recommended a simplified type of hospital-based record keeping.

Question 6E (2). What guidelines, if any, were issued at that time?

Answer 6E (2). The guideline listed a number of standard items which should be serially recorded and followed.

Question 6E (3). Has the Commission's positions on the maintenance of registries changed since that time?

(4). If so, in what respect?

Answer 6E (3 and 4). During the 1979 meeting of the Commission the question of registries was reviewed and the consensus appears to be that computer-based registries may be of assistance in predicting failure trends and modes for specified brands and models of cardiac pacemakers. However, no specific new guidelines have been published by the Commission.

Question 7A. The VA Central Office Pacemaker Committee was established in 1975 for the purpose, in part, of establishing a pacemaker registry.

What is the reason for the great delay in issuing circular 10–79–268 to accomplish this purpose?

Answer 7A. Among the factors which delayed publication of a VA pacemaker registry surveillance system were the following?

(1) Evolving concepts of the registry and surveillance system.

(2) Need to test and evaluate services from a number of commercial firms, as well as existing registries such as those supported by FDA.

(3) Concurrent testing and development of an in-house electronic monitoring program for one of the VA medical districts.

(4) Decision that pacemaker monitoring services should not be obtained from a firm associated with pacemaker manufacturing to avoid corporate conflict of interest.

(5) Limitation of resources to evaluate the state of the art and develop a tool satisfactory to both clinicians and administrators.

Question 7B. What instructions has this Committee issued to VA medical centers with respect to procurement of pacemakers?

C. What instructions has this Committee issued to VA medical centers with respect to the monitoring and followup of pacemaker patients?

D. What instructions has this Committee issued to VA medical centers with respect to the surveillance options that were/are available (in-house or other) with respect to monitoring and followup of pacemaker patients?

Answer 7B, C, and D. The VA Center Office Pacemaker Committee is an advisory committee only and does not make or implement policy. However, its deliberations and recommendations to Central Office have formed the nucleus of all VA circulars and other pronouncements dealing with the VA's cardiac pacemaker program.

Question 7E. When was telephonic monitoring first considered by the Committee?

Answer 7E. The Committee first considered telephonic monitoring in 1976.

Question 8. When will the cost-effectiveness of contracting for the development, operation, and maintenance of the VA's planned pacemaker registry be determined? Please provide the Committee with a report when that decision is made.

Answer 8. Resources for a study to compare the cost-effectiveness of in-house vs contract telephonic monitoring and pacemaker registry development, operation and maintenance have been requested in the fiscal year 1982 budget. In addition, the VA Central Office Pacemaker Committee will develop a protocol to obtain preliminary information concerning this matter. The Committee will be provided a report on the outcome of these efforts as soon as they are available.

Question 9A. Are all of the 90 designated cardiac pacemaker prostheses referral centers (CPPR's) operating at this time?

Answer 9A. At the present time there are 94 officially designated CPPRs in operation throughout the system.

Question 9B. Is there at least one biomedical engineer on the staff of each such center?

Answer 9B. Sixty-one (61) of these 94 CPPRs have biomedical engineer positions on their staffs. All those CPPRs that do not have biomedical engineers have one or more biomedical technicians. In addition to these technicians, those centers without biomedical engineers on site can utilise bioengineering support from neighboring VAMCs, an affiliated university medical center, or VA Central Office.

Question 9C. If not, why not?

Answer 9C. The reasons for not having a bioengineer at a given medical center vary, but the principal ones have to do with the ready availability of such expertise from other sources and the cost of such personnel. As indicated in B. above, however, there is at least one biomedical technician at each CPPR.

Question 10A. Under circular 10-79-269, how do the designated CPPR centers go about obtaining telephonic surveillance services from decentralized contractors?

Answer 10A. When a VA CPPR center determines that telephonic pacemaker surveillance is necessary, but cannot be provided through in-house capability, a requirement for this service is submitted to that VA medical center's Supply Service. The Supply Service will in turn process that request in accordance with procurement regulations and with instructions contained in the current VA decentralized contract for telephonic monitoring services.

Question 10B. Is this activity coordinated by the Supply Service or by the Surgical Service?

Answer 10B. As outlined in A. above, the need for telephonic pacemaker monitoring services is determined by the responsible clinical service. The VAMC Supply Service then processes the request in accordance with pertinent regulations.

Question 11A. With respect to the VA's planned pacemaker and patient registry, circular 10-79-268 requires VA medical centers to provide to Central Office very specific information about the total VA pacemaker population. This information is not being forwarded to the data processing center in St. Paul.

Is the computer system currently operating in St. Paul capable of handling this additional load?

Answer 11A. Yes. the computer system currently operating in St. Paul is capable of handling the cardiac pacemaker workload.

Question 11B. Will any computer capability have to be diverted from another task in order to process the great amount of information on the pacemaker population with respect to its characteristics and any defects occurring in implanted pacemakers?

Answer 11B. No, it will not be necessary to divert computer capability from any other task in order to process the pacemaker information as currently specified. In order to develop the system, i.e., write and test the necessary programs, priorities at the DPC were shifted somewhat. The development process was the most resource-consuming phase of the project. Once the system is installed, its operation will have very little impact on the DPC. Coding sheets from the hospitals will be key-entered and the Registry updated on a monthly basis. The reporting cycle will be provided each quarter. Resources required for this operation will be minimal. Because data have been collected since December 1979, the first few cycles will involve more key-entry and computer time, but even this initial processing is not expected to cause any substantial problems for the DPC.

Question 12A. Does the VA reimplant, or has it reimplanted, pacemakers in the same patient?

Answer 12A. The VA has not maintained any statistics dealing with the reimplantation of pacemakers in the same patient.

However, such a practice is considered medically acceptable under certain circumstances, e.g. when the reason(s) for explanation are not related to the pacemaker performance and the pacemaker can be expected to continue functioning for a prolonged period of time.

Question 12B. Please provide the Committee with the VA's policy guidelines with respect to reimplantation of pacemakers in the same patient.

Answer 12B. The VA has not issued any formal policy guidelines concerning this matter. This is felt to be within the purview of the responsible physician's professional judgment.

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